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Rx Only

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Bioness®
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NESS
L300®Plus

User's Guide

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L300®Plus

User's Guide

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Patents Pending
Aspects of this device are covered by several patents and patent applications, including US Pat 7,899,556.

Disclaimer
Bioness Inc and its affiliates shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or repair of Bioness Inc products. Bioness Inc does not accept any responsibility for any damage caused to its products, either directly or indirectly, as a result of use and/or repair by unauthorized personnel.

Environmental Policy

Service personnel are advised that when changing any part of the NESS L300 Plus System, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. For more detailed information regarding these recommended procedures, please contact Bioness Inc. Bioness Inc is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

Bioness Client Relations Department: Telephone: (800) 211-9136, Option 2; or (661) 362-4850, Option 2.

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List of Symbols

	Caution or Warning
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must not be Disposed of with Other Household Waste
	Consult Instructions for Use
SN	Serial Number
REF	Re-Order Number
LOT	Lot Number
	Complies with United States and Canadian Product Safety Standards
CE 0473	Complies with the European Union Medical Device Directive
	Single Patient Use

Introduction

Central nervous system (CNS) injuries and diseases often cause a gait disorder called foot drop. People who have foot drop are unable to raise their foot while walking. They often drag their foot, resulting in instability and increased effort during gait. Many people with CNS injuries/diseases also suffer from thigh muscle weakness. Weak thigh muscles can cause considerable difficulties with flexing or extending the knee during ambulation.

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

This NESS L300 Plus *User's Guide* describes:

- Important safety information about the NESS L300 Plus System.
- The components of the NESS L300 Plus System.
- How to set up, operate, and maintain the NESS L300 Plus System.
- Troubleshooting information.

Be sure to review this guide with your clinician before using the NESS L300 Plus System.

If you have clinical or technical questions, consult your clinician or the Bioness Client Relations Department at (800) 211-9136, Option 3, or visit the Bioness website: www.bioness.com.

CAUTION: Do not put on or operate the NESS L300 Plus System before being properly fitted and trained by a certified clinician.

Device Description and Safety Information

Device Description

The NESS L300 Plus System consists of four main components:

- **L300 Functional Stimulation (FS) Cuff with L300 Radio Frequency (RF) Stim Unit**—used to stimulate the nerves that control the muscles of the lower leg.
- **Thigh FS Cuff with Thigh RF Stim Unit**—used to stimulate the nerves that control the muscles of the thigh.
- **Intelli-Sense Gait Sensor**—used to sense and wirelessly transmit heel events in the affected leg.
- **L300 Plus Control Unit**—used to wirelessly control and monitor the NESS L300 Plus System.

These components communicate wirelessly to provide synchronized ankle dorsiflexion and knee flexion or extension.

Indications for Use

The NESS L300 Plus System is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease.

During gait, the NESS L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and knee flexion or extension; thus, it may improve the individual's gait.

The NESS L300 Plus System may also:

- Facilitate muscle re-education.
- Prevent or retard disuse atrophy.
- Maintain or increase joint range of motion.
- Increase local blood flow.

Contraindications

- Patients with a demand-type cardiac pacemaker, defibrillator, or any electrical or metallic implant should not use the NESS L300 Plus System.
- The NESS L300 Plus System should not be used on a leg where a cancerous lesion is present or suspected.
- The NESS L300 Plus System should not be used on a leg with a regional disorder, such as a fracture or dislocation, which could be adversely affected by motion from the stimulation.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The L300 and Thigh FS Cuffs should not be worn over swollen, infected, or inflamed areas or skin eruptions, such as phlebitis, thrombophlebitis, and varicose veins.
- Simultaneous connection of the NESS L300 Plus System to the patient and high-frequency surgical equipment may result in skin burns where the stimulator electrodes touch and damage to the L300 and Thigh RF Stim Units.
- The NESS L300 Plus System should only be configured by an authorized clinician.

Precautions

- Inflammation in the region of the L300 and Thigh FS Cuffs may be aggravated by motion, muscle activity, or pressure from the FS Cuffs. Stop using the NESS L300 Plus System until any inflammation is gone.
- Use caution if you have a suspected or diagnosed heart problem.
- Use caution if you have suspected or diagnosed epilepsy.
- Use the L300 and Thigh FS Cuffs with caution:
    - If you have a tendency to bleed heavily following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over areas of the skin that lack normal sensation.

- Obtain physician clearance prior to use if you have an alteration in normal arterial or venous flow in the region of the L300 and/or Thigh FS Cuffs because of local insufficiency (insufficient blood flow), occlusion (a blood flow blockage), arteriovenous fistula for the purpose of hemodialysis (an abnormal connection between an artery and vein), or a primary disorder of the vasculature (a disease of the blood vessels: arteries, veins, and lymphatics).
- Obtain physician clearance before stimulating an area with a structural deformity.
- The safe use of the NESS L300 Plus System during pregnancy has not been established.
- Keep the NESS L300 Plus System out of the reach of children.
- The L300 and Thigh FS Cuffs are to be worn only on the leg of the patient for whom they have been fitted. They should not be worn by anyone else or on any other part of the body.
- Skin problems where the L300 and Thigh FS Cuffs are worn may be aggravated by the NESS L300 Plus System.
- Some patients may experience a skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. In some cases, irritation may be avoided by having your clinician change the stimulation parameters, type of electrodes used, or electrode placement.
- After removing the L300 and Thigh FS Cuffs, it is normal for the areas under the electrodes to be red and indented. The redness should disappear in approximately one hour. Persistent redness, lesions, or blisters are signs of irritation. Stop using the NESS L300 Plus System until any irritation is gone.

- Do not use the NESS L300 Plus System without electrodes.
- Use only electrodes supplied by Bioness Inc.
- Change the electrodes at least every two weeks.
- Only the treating clinician should determine electrode placement and stimulation settings.
- Turn off the NESS L300 Plus System before removing, replacing, and wetting the electrodes.
- Turn off the NESS L300 Plus System before putting on the L300 and Thigh FS Cuffs. Do not turn on the NESS L300 Plus System until the FS Cuffs are fastened in place.
- Turn off the NESS L300 Plus System before driving, operating machinery, or performing any activity in which involuntary muscle contractions could injure you.
- Turn off the NESS L300 Plus System when at a refueling place. Do not use the NESS L300 Plus System near flammable fuel, fumes, or chemicals.
- Stop using the NESS L300 Plus System and consult your clinician if stimulation does not start at the correct time during gait.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Do not leave the NESS L300 Plus System stored where temperatures may exceed the acceptable environmental range: -25°C to +55°C (-13°F to +131°F). Temperature extremes can damage the components.
- The NESS L300 Plus System needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual. See Chapter 3 and the Appendix.

- Do not attempt to repair your NESS L300 Plus System. Changes or modifications to the NESS L300 Plus System components not expressly approved by Bioness Inc could void the user's authority to operate the equipment.

Contact the Bioness Client Relations Department, Option 3, if you experience a clinical or technical problem not covered in this guide.

CAUTION: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 300 pounds (136 kilograms).

CAUTION: Do not use the Intelli-Sense Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.

Adverse Reactions

In the unlikely event that any of the following occurs, stop using your NESS L300 Plus System immediately and consult your physician:

- Signs of significant irritation or pressure sores where the L300 and/or Thigh FS Cuffs contact the skin.
- A significant increase in muscle spasticity.
- A feeling of heart-related stress during stimulation.
- Swelling of the leg, knee, ankle, or foot.
- Any other unanticipated reaction.

Skin irritations and burns have been reported with the use of powered muscle stimulators.

Skin Care Guidelines

In the absence of proper skin care, extended use of electrical stimulation may cause skin irritation or a skin reaction to the NESS L300 Plus System electrodes or the L300 and/or Thigh FS Cuffs.

To promote healthy skin with long-term use of the NESS L300 Plus System, it is important to follow a daily skin-care routine:

- Clean the skin where the electrodes touch with a wet washcloth. If any oils or lotions are on the skin, then clean with soap and water. Rinse well.
- Always check the skin for redness or a rash when putting on and taking off the L300 and Thigh FS Cuffs.
- Wet the cloth electrodes before use and after every three to four hours of use.

- Replace the electrodes at least every two weeks, even if they appear to be in good condition.
- Store the L300 hydrogel electrodes with the protective plastic covers attached. Do not allow the hydrogel electrodes to dry.
- Store the cloth electrodes where they can air dry.
- Excess body hair where the L300 hydrogel electrodes adhere may reduce electrode contact with the skin. If necessary, remove excess body hair with an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
- When positioning the L300 and Thigh FS Cuffs, make sure the electrodes uniformly contact the skin.
- Ventilate the skin by removing the L300 and Thigh FS Cuffs for at least 15 minutes every 3 to 4 hours.

If skin irritation or a skin reaction occurs, stop using your NESS L300 Plus System immediately. Contact your clinician or dermatologist, and the Bioness Client Relations Department, Option 3. Resume use only when the skin is completely healed. Then follow a skin conditioning protocol per the recommendation of your health-care specialist.

If you have any questions or concerns, please call the Bioness Client Relations Department at (800) 211-9136, Option 3.

Environmental Conditions that Affect Use

Radio Frequency (RF) Communication Information

Several components of the NESS L300 Plus System communicate via radio communication and have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (RF Devices) of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for assistance.

The antenna for each transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Portable and mobile RF communications equipment can affect the NESS L300 Plus System.

Conformity Certification

The NESS L300 Plus System complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

Travel and Airport Security

The NESS L300 Plus system charger is compatible with Australian, U.K., European Union, and U.S. voltages: 110/220 V, 50/60 Hz.

Turn off your NESS L300 Plus System before going through airport security. Wear loose clothing so that you can easily show the security person your NESS L300 Plus System. The NESS L300 Plus System will likely set off the security alarm. Be prepared to remove the NESS L300 Plus System so that security can scan it, or ask for the system to be scanned if you do not want to remove it. You may want to carry a copy of your NESS L300 Plus System prescription. A prescription can be useful when passing through customs as well.

To request a copy of your prescription, call the Bioness Client Relations Department: Telephone: (800) 211-9136, Option 2; or (661) 362-4850, Option 2. A Bioness representative can fax or mail you a copy.

Note: The NESS L300 Plus System contains radio transmitters. The Federal Aviation Administration rules require that all radio-transmitting devices be turned off during flight.

Electromagnetic Emissions

The NESS L300 Plus System needs special precautions regarding electromagnetic compatibility (EMC). The system needs to be installed and put into service according to the EMC information provided in this manual. See Appendix.

The NESS L300 Plus System was tested and certified to use the following:

- DC power supply as provided by Bioness Inc, manufactured by FRIWO, Part No. FW7555M/05.
- W cable (3-way splitter) as provided by Bioness Inc, Model No. L3P-5A00. Manufactured by Tamuz Electronics Ltd.

Warnings

- Do not use the NESS L300 Plus System within three feet of shortwave or microwave therapy equipment. Such equipment may produce instability in the output of the L300 and Thigh RF Stim Units.
- Remove the NESS L300 Plus System before undergoing any diagnostic or therapeutic medical procedure such as x-ray examination, ultrasound, Magnetic Resonance Imaging (MRI), etc.
- The NESS L300 Plus System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the NESS L300 Plus System as replacement parts for internal components, may result in increased emissions or decreased immunity of the NESS L300 Plus System.

- The use of the accessory, transducer, or cable with equipment and systems other than those specified may result in increased emissions or decreased immunity of the NESS L300 Plus System.
- The NESS L300 Plus System may be interfered with by other equipment, even if that other equipment complies with CISPR (International Special Committee on Radio Interference, International Electrotechnical Commission) emission requirements.

NESS L300 Plus System Kits

NESS L300 Plus System Kit

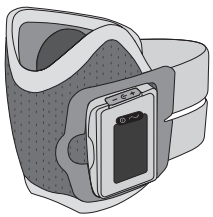
System Components

- L300 Plus Control Unit
- L300 FS Cuff and RF Stim Unit
- Thigh FS Cuff and RF Stim Unit
- Intelli-Sense Gait Sensor

Accessories

- System Charger Set
- Control Unit Neck Strap
- Control Unit Wrist Strap
- Control Unit Belt Pouch

L300 Plus Control Unit



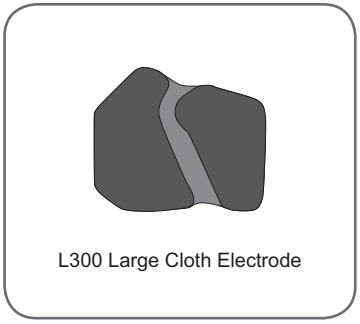
L300 FS Cuff and RF Stim Unit

Thigh FS Cuff and RF Stim Unit

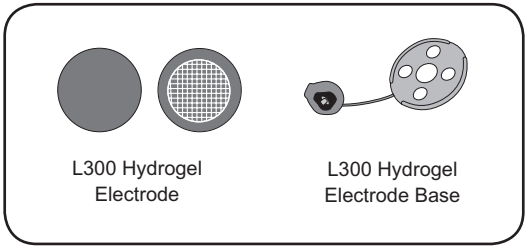
Intelli-Sense Gait Sensor

- Replacement Battery, Gait Sensor
- Gait Sensor Pads
- Shoe Spacers
- Thigh Elongation Bar Locks
- Thigh Electrode Marking Rings
- Large Cloth Electrode*
- L300 Hydrogel Electrodes and Bases*
- L300 Cloth Electrodes and Bases*
- Thigh Cloth Electrodes
- Cloth Electrode Mesh Bag
- Carrying Case
- L300 Plus *User's Guide*
- User's Reference Card

**One L300 electrode type included, as determined by your clinician.*

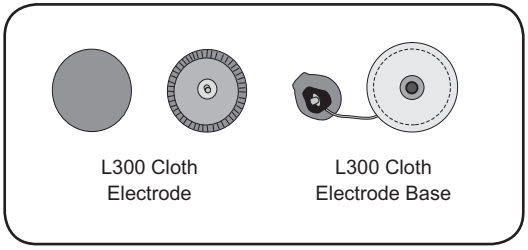


L300 Large Cloth Electrode



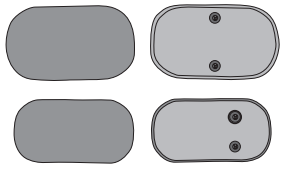
L300 Hydrogel Electrode

L300 Hydrogel Electrode Base

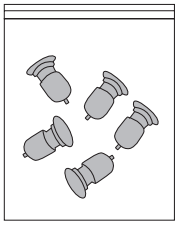


L300 Cloth Electrode

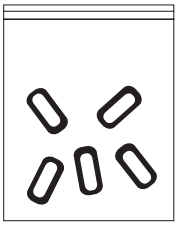
L300 Cloth Electrode Base



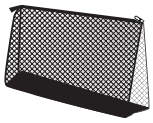
Thigh Cloth Electrodes



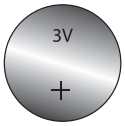
Thigh Elongation Bar Locks



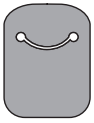
Thigh Electrode Marking Rings



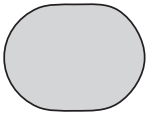
Cloth Electrode Mesh Bag



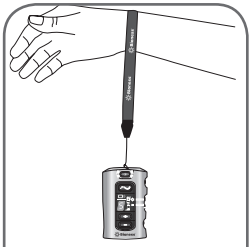
Replacement Battery, Gait Sensor



Shoe Spacer

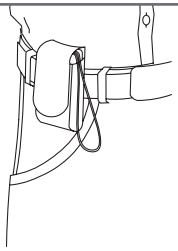


Gait Sensor Pad

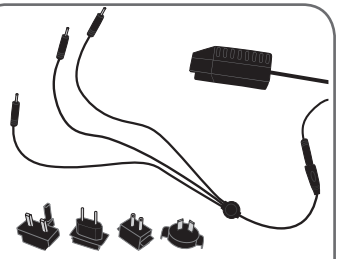


Control Unit Wrist Strap

Control Unit Neck Strap



Control Unit Belt Pouch



System Charger Set

NESS L300 Plus System Upgrade Kit

The NESS L300 Plus System Upgrade Kit is for individuals who have a NESS L300 Foot Drop System.

System Components

- L300 Plus Control Unit
- Thigh FS Cuff and RF Stim Unit

Accessories

- System Charger Set
- Thigh Elongation Bar Locks
- Thigh Electrode Marking Rings
- Thigh Cloth Electrodes
- Carrying Case
- Control Unit Neck Strap
- Control Unit Wrist Strap
- Control Unit Belt Pouch
- Cloth Electrode Mesh Bag
- L300 Plus *User's Guide*
- User's Reference Card

IMPORTANT! Bring your NESS L300 Foot Drop System to your L300 Plus fitting session.

NESS L300 Plus System

L300 Functional Stimulation (FS) Cuff

The L300 FS Cuff fits on the affected leg below the knee. See Figure 5-1. The L300 FS Cuff is designed to facilitate dorsiflexion of the foot. It is lightweight, easy to put on with one hand, and can be worn under loose clothing.

The L300 FS Cuff features a radio frequency (RF) stimulation unit that communicates wirelessly with the L300 Plus Control Unit and Intelli-Sense Gait Sensor.

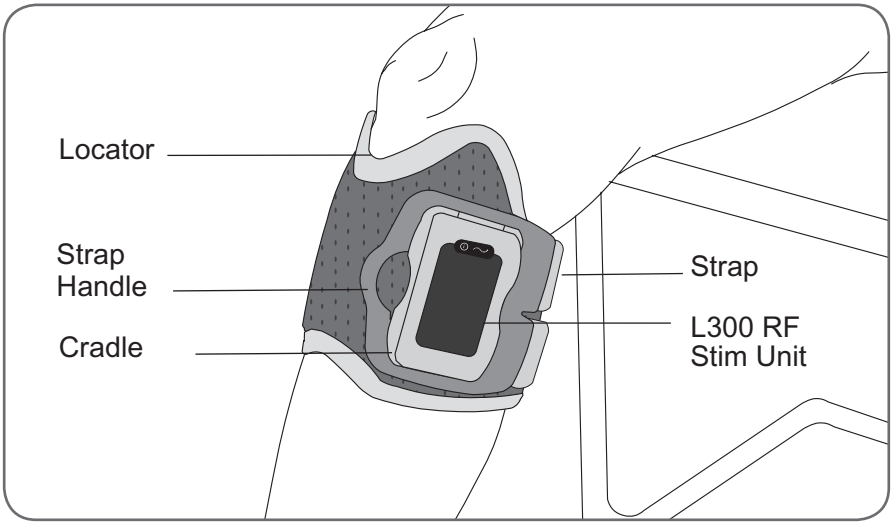


Figure 5-1: L300 FS Cuff.

Locator

The locator fits under the kneecap of the affected leg. The locator is used to accurately place the L300 FS Cuff on the leg, and to ensure repeatable electrode contact.

Cradle

The cradle holds the L300 RF Stim Unit. The L300 RF Stim Unit snaps in and out of the cradle.

Note: The L300 RF Stim Unit should only be removed for maintenance and when cleaning the L300 FS Cuff.

Strap

The L300 FS Cuff strap is adjustable and has a flexible handle, which fits over the cradle to fasten.

L300 Electrodes and Electrode Bases

The following electrodes may be used with the L300 FS Cuff:

- Large Cloth Electrode, L300 systems.
- L300 Hydrogel Electrodes and Hydrogel Electrode Bases.
- L300 Cloth Electrodes and Cloth Electrode Bases.

The electrodes attach to the inside of the L300 FS Cuff. Your clinician will determine the type of electrodes most appropriate for you and then fit the electrodes to your L300 FS Cuff.

CAUTION: Do not wear the L300 FS Cuff without electrodes.

L300 RF Stim Unit

The L300 RF Stim Unit generates the electrical stimulation used to dorsiflex the foot. It responds to wireless signals from the L300 Plus Control Unit and the Intelli-Sense Gait Sensor to turn stimulation on/off.

The L300 RF Stim Unit includes a status light, a stimulation light, and a rechargeable battery. The battery charging port is located at the top of the L300 RF Stim Unit, under the flexible cover. See Figure 5-2.

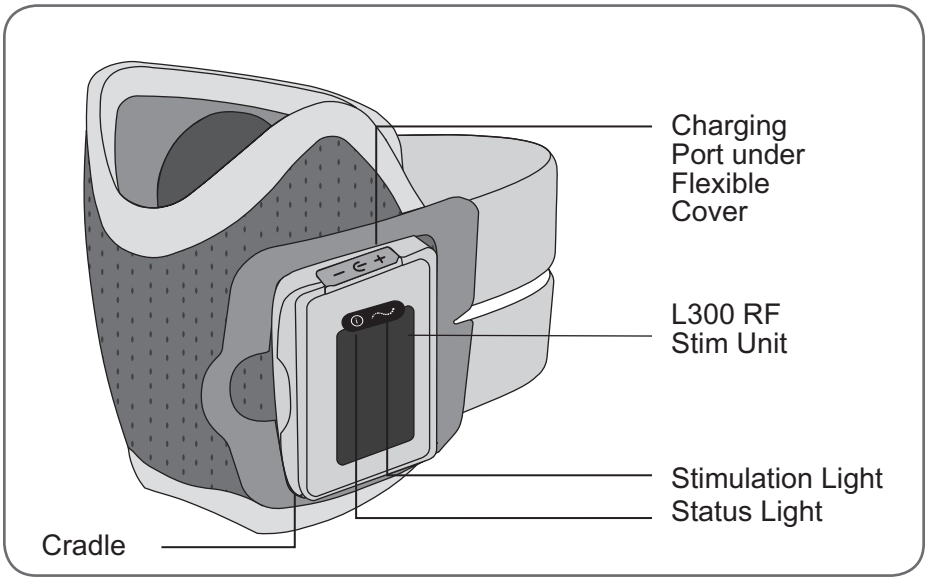


Figure 5-2: L300 RF Stim Unit.

The L300 RF Stim Unit emits visual and/or audio alerts when:

- Stimulation is on.
- RF communication with the L300 RF Stim Unit fails.
- The L300 RF Stim Unit battery charge level is low.
- The L300 RF Stim Unit battery is charging.
- The L300 RF Stim Unit malfunctions. See Table 5-1.

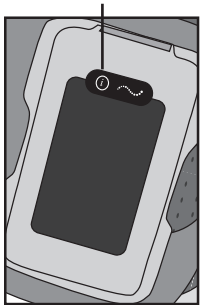
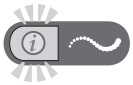
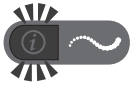
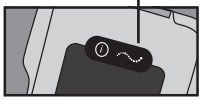
L300 RF Stim Unit	Display	Description	Definition
Status Light 		FLASHES GREEN	System is On
		FLASHES YELLOW	Low Battery
		ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
		SOLID GREEN	Battery Fully Charged
		FLASHES RED	RF Communication Failure
		SOLID RED	Malfunction
Stimulation Light 		FLASHES YELLOW SLOWLY	Stimulation is Off
		FLASHES YELLOW RAPIDLY	Stimulation is On

Table 5-1: L300 RF Stim Unit displays.

Thigh FS Cuff

The Thigh FS Cuff is a lightweight, low-profile orthosis designed to assist with knee flexion or extension. See Figure 5-3. The Thigh FS Cuff fits above the affected knee, centered on the back or front of the thigh.

The Thigh FS Cuff features an RF stimulation unit that communicates wirelessly with the L300 Plus Control Unit and Intelli-Sense Gait Sensor.

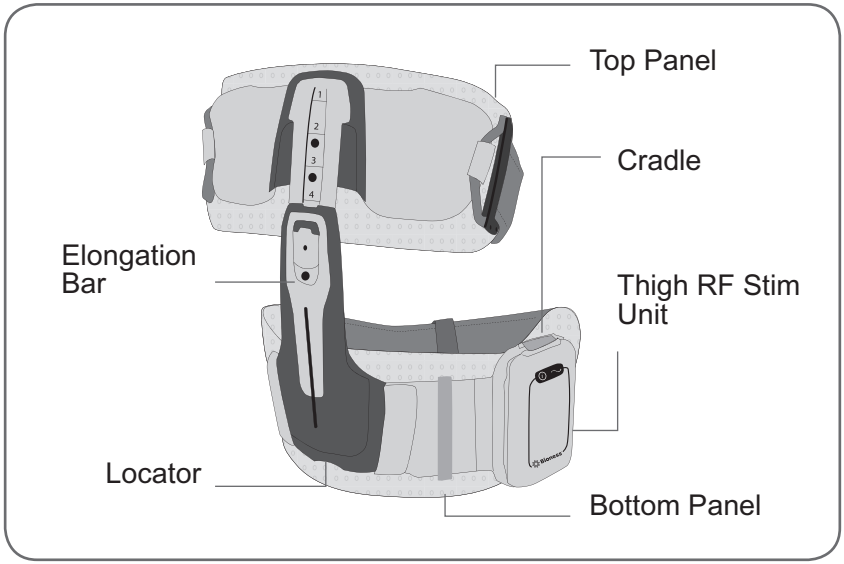


Figure 5-3: Thigh FS Cuff.

Panels

The Thigh FS Cuff features two panels. The top panel fits higher on the thigh. The bottom panel fits lower on the thigh. The bottom panel has a cradle for the Thigh RF Stim Unit.

Elongation Bar

The elongation bar connects the top and bottom Thigh FS Cuff panels. Your clinician will adjust the elongation bar and lock it.

Locator

The Thigh FS Cuff locator should rest on the center of the thigh, three finger widths from the knee of the affected leg. The locator is used to accurately place the Thigh FS Cuff on the leg, and to ensure repeatable electrode contact.

Cradle

The cradle holds the Thigh RF Stim Unit. The Thigh RF Stim Unit snaps in and out of the cradle.

Note: The Thigh RF Stim Unit should only be removed for maintenance and when cleaning the Thigh FS Cuff.

Thigh Cloth Electrodes

The Thigh FS Cuff uses two cloth electrodes to provide electrical stimulation. The large Thigh cloth electrode snaps to the Thigh FS Cuff top panel. The small Thigh cloth electrode snaps to the Thigh FS Cuff bottom panel. See Figure 5-4.

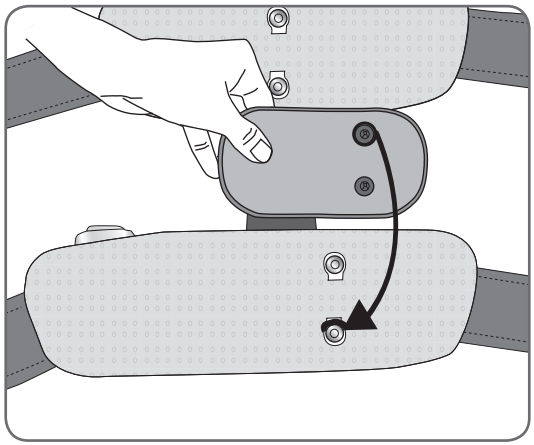


Figure 5-4: Snapping the small Thigh cloth electrode to the bottom panel.

CAUTION: Do not wear the Thigh FS Cuff without the cloth electrodes.

Thigh RF Stim Unit

The Thigh RF Stim Unit generates the electrical stimulation used to flex or extend the knee. It responds to wireless signals from the L300 Plus Control Unit and the Intelli-Sense Gait Sensor to turn stimulation on/off.

The Thigh RF Stim Unit includes a status light, a stimulation light, and a rechargeable battery. See Figure 5-5. The battery charging port is located at the top of the Thigh RF Stim Unit, under the flexible cover.

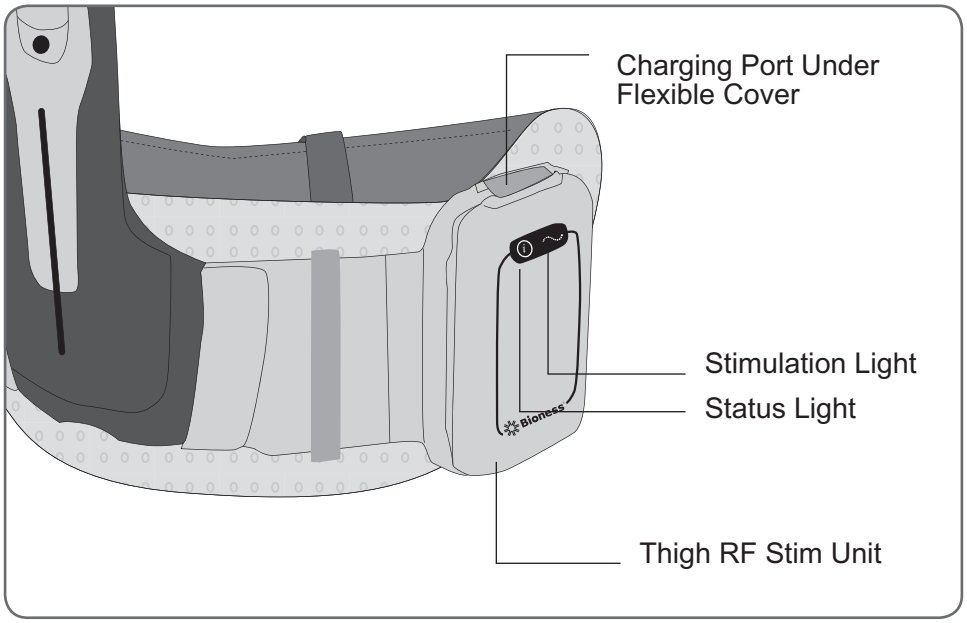


Figure 5-5: Thigh RF Stim Unit.

The Thigh RF Stim Unit emits visual and/or audio alerts when:

- Stimulation is on.
- RF communication with the Thigh RF Stim Unit fails.
- The Thigh RF Stim Unit battery charge level is low.
- The Thigh RF Stim Unit battery is charging.
- The Thigh RF Stim Unit malfunctions. See Table 5-2.

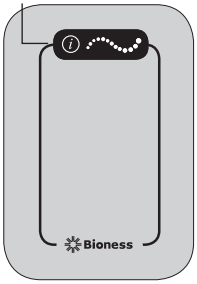
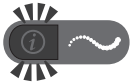
Thigh RF Stim Unit	Display	Description	Definition
Status Light 		FLASHES GREEN	System is On
		FLASHES YELLOW	Low Battery
		ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
		SOLID GREEN	Battery Fully Charged
		FLASHES RED	RF Communication Failure
		SOLID RED	Malfunction
Stimulation Light		FLASHES YELLOW SLOWLY	Stimulation is Off
		FLASHES YELLOW RAPIDLY	Stimulation is On

Table 5-2: Thigh RF Stim Unit displays.

Intelli-Sense Gait Sensor

The Intelli-Sense Gait Sensor features a pressure sensor and a transmitter. See Figure 5-6.

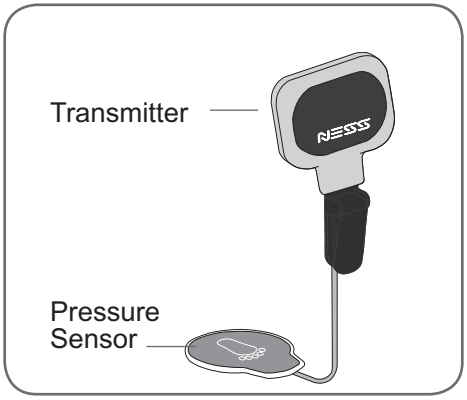


Figure 5-6: Intelli-Sense Gait Sensor.

The pressure sensor:

- Fits under the insole of the shoe of the affected leg, attached to a gait sensor pad. See Figure 5-7.
- Detects when the foot is in the air and on the ground.

CAUTION: Do not use the Intelli-Sense Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.

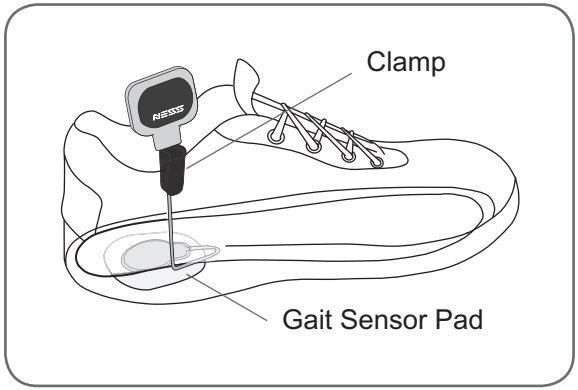


Figure 5-7: Intelli-Sense Gait Sensor in a left shoe.

The transmitter:

- Is worn clamped to the inner rim of the shoe. See Figure 5-7.
- Communicates wirelessly with the L300 and Thigh RF Stim Units.

The Intelli-Sense Gait Sensor can be transferred to a different shoe, or additional Intelli-Sense Gait Sensors may be purchased for different shoes. You do not need to detach the Intelli-Sense Gait Sensor between uses.

The Intelli-Sense Gait Sensor is powered by a small non-rechargeable battery. The battery may need to be replaced after approximately six months of use.

CAUTION: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 300 pounds (136 kilograms).

L300 Plus Control Unit

The L300 Plus Control Unit is used to:

- Turn on/off the NESS L300 Plus System.
- Test the position of the FS Cuffs.
- Select an operating mode (gait, training, or standby).
- Fine-tune stimulation intensity.
- Mute/un-mute system audio alerts.
- Turn off visual alerts.
- Turn on/off audio feedback during stimulation.
- Monitor system status. See Figure 5-8 and Table 5-3.

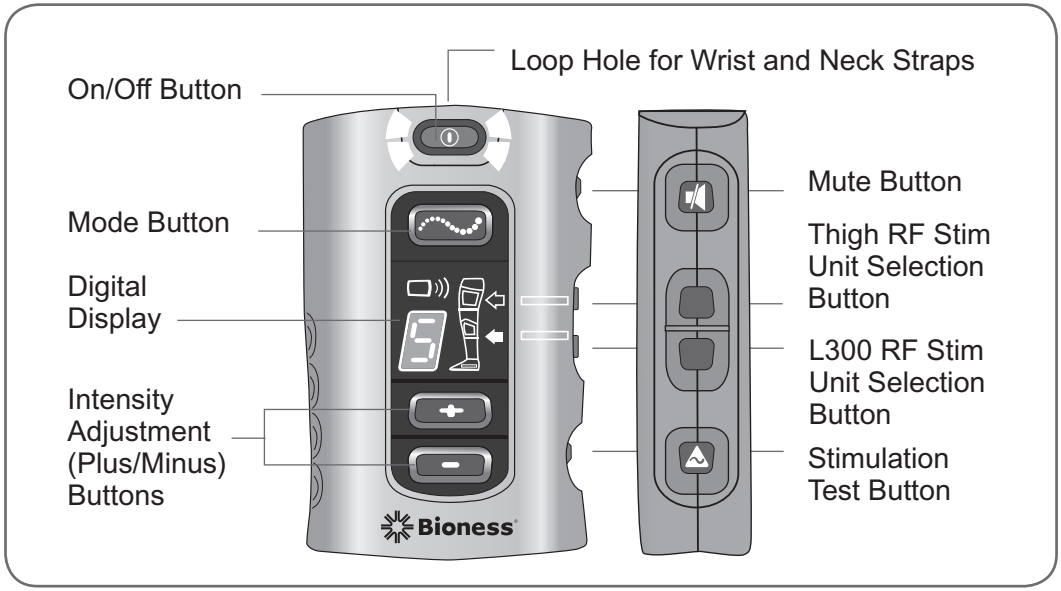


Figure 5-8: L300 Plus Control Unit operating buttons and digital display.

The L300 Plus Control Unit communicates wirelessly with the L300 and Thigh RF Stim Units. It is powered by a single rechargeable AAA NiMH battery, and is small enough to wear on a neck strap or in a belt pouch.

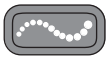
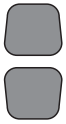
L300 Plus Control Unit	Operating Button	Description	Function
		On/Off	Turns On/Off the System
		Mode	Selects Standby, Gait, or Training Mode
		Intensity Adjustment (Plus/Minus)	Increases Stimulation Intensity Decreases Stimulation Intensity
		RF Stim Unit Selection	Top: Selects the Thigh RF Stim Unit. Bottom: Selects the L300 RF Stim Unit
		Mute	Mutes/Un-Mutes the Control Unit Audio Alerts; Turns Off the Visual and Audio Indicators in the Selected RF Stim Unit; Turns On/Off Audio Feedback During Stimulation
		Stimulation Test	Tests Stimulation for the Selected RF Stim Unit

Table 5-3: L300 Plus Control Unit operating buttons.

Operating Modes

The L300 Plus System has three operating modes: standby, gait, and training.

Standby Mode

In standby mode, the NESS L300 Plus System is on and waiting for commands. Stimulation is off.

Gait Mode

Gait mode is used when walking. In gait mode, the Intelli-Sense Gait Sensor signals the L300 and Thigh RF Stim Units when the heel leaves the ground and when the heel contacts the ground. Stimulation in the L300 and Thigh RF Stim Units respond as programmed by the clinician.

Training Mode

Training mode is used to train the muscles when not walking (for example, sitting or lying down). Training mode works independently of the Intelli-Sense Gait Sensor. Stimulation is delivered in cycles pre-set by the clinician.

Training mode is designed to:

- Facilitate muscle re-education.
- Prevent or retard disuse atrophy of the lower leg and thigh muscles.
- Maintain or improve range of motion of the ankle and knee joints.
- Improve local blood circulation.

Digital Display and Indicator Lights

The L300 Plus Control Unit digital display and indicator lights indicate:

- Stimulation intensity level.
- Operating mode.
- Battery charge status.
- Electronic registration status.
- RF Stim Unit selected.
- Error messages. See Figure 5-9 and Tables 5-4 through 5-9.

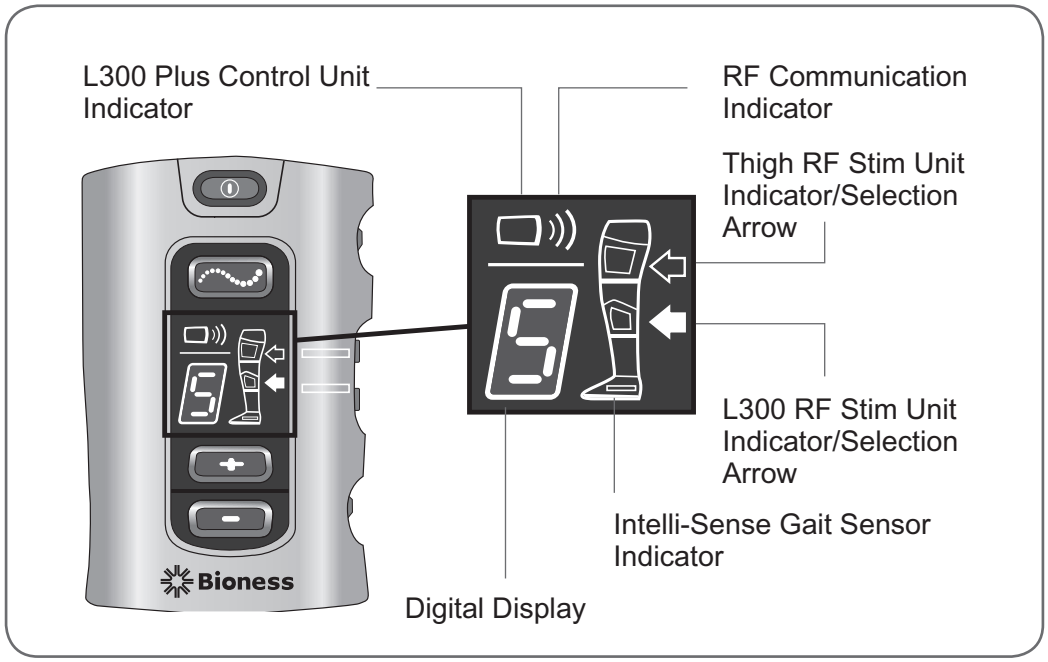


Figure 5-9: L300 Plus Control Unit digital display and indicators.

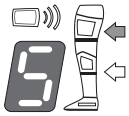
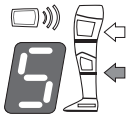
Display	Description	Definition
	On/Off Button FLASHES GREEN	System is On
	Mode Button FLASHES YELLOW SLOWLY	Stimulation is Off
	Mode Button FLASHES YELLOW RAPIDLY	Stimulation is On
	Displays 0–9	Stimulation Intensity Level
	Intensity Level and Letter “t” Alternate	Training Mode is On
	GREEN Arrow by Thigh RF Stim Unit	Thigh RF Stim Unit Selected
	GREEN Arrow by L300 RF Stim Unit	L300 RF Stim Unit Selected

Table 5-4: L300 Plus Control Unit operating displays.

Display	Description	Definition
	Thigh RF Stim Unit Indicator FLASHES RED	Faulty Electrode Contact in Thigh FS Cuff
	L300 RF Stim Unit Indicator FLASHES RED	Faulty Electrode Contact in L300 FS Cuff
	Thigh RF Stim Unit Indicator is SOLID RED	Thigh RF Stim Unit Software or Hardware Malfunction
	L300 RF Stim Unit Indicator is SOLID RED	L300 RF Stim Unit Software or Hardware Malfunction
	L300 Plus Control Unit Indicator is SOLID RED	L300 Plus Control Unit Software or Hardware Malfunction
	Gait Sensor Indicator is SOLID RED	Intelli-Sense Gait Sensor Software or Hardware Malfunction

Table 5-5: L300 Plus Control Unit component error displays.

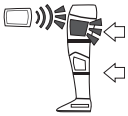
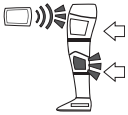
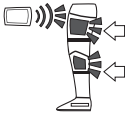
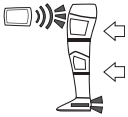
Display	Description	Definition
	Thigh RF Stim Unit Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, Thigh RF Stim Unit
	L300 RF Stim Unit Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, L300 RF Stim Unit
	Thigh RF Stim Unit, L300 RF Stim Unit, and RF Communication Indicators ALTERNATELY FLASH RED	RF Communication Failure, L300 and Thigh RF Stim Units
	Intelli-Sense Gait Sensor Indicator and RF Communication Indicator ALTERNATELY FLASH RED	RF Communication Failure, Intelli-Sense Gait Sensor

Table 5-6: L300 Plus Control Unit RF communication errors.

Note: The L300 Plus Control Unit, L300 RF Stim Unit, and Thigh RF Stim Unit must be within RF communication range to communicate wirelessly. The communication range is approximately 10 feet (3 m). If RF communication fails, the RF communication indicator on the L300 Plus Control Unit will FLASH RED.

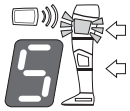
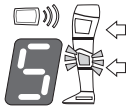
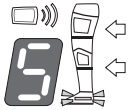
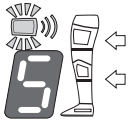
Display	Description	Definition
	Thigh RF Stim Unit Indicator FLASHES YELLOW	Thigh RF Stim Unit Low Battery
	L300 RF Stim Unit Indicator FLASHES YELLOW	L300 RF Stim Unit Low Battery
	Intelli-Sense Gait Sensor Indicator FLASHES YELLOW	Intelli-Sense Gait Sensor Low Battery
	L300 Plus Control Unit Indicator FLASHES YELLOW	L300 Plus Control Unit Low Battery

Table 5-7: L300 Plus Control Unit low battery displays.

Display	Description	Definition
	ALTERNATING GREEN Arches	Registration in Process
	Letter "C"	Registration Complete
	Letter "E"	Registration Error

Table 5-8: L300 Plus Control Unit electronic registration displays.

Display	Description	Definition
	ROTATING GREEN Circle	L300 Plus Control Unit Charging
	Horizontal GREEN Line	L300 Plus Control Unit Fully Charged
	Letter "E" FLASHES while Charging	Charging Error

Table 5-9: L300 Plus Control Unit charging displays and definitions.

Audio Indicators

The L300 Plus Control Unit beeps to indicate:

- The NESS L300 Plus System is on.
- A button was pressed.
- Low battery.
- An error.

L300 Plus Accessories

L300 Electrodes and Bases

The L300 electrodes deliver the electrical stimulation used to dorsiflex the foot.

Three types of electrodes may be used:

- L300 Large Cloth Electrode.
- L300 Hydrogel Electrodes with Hydrogel Electrode Bases.
- L300 Cloth Electrodes with Cloth Electrode Bases. See Figure 6-1.

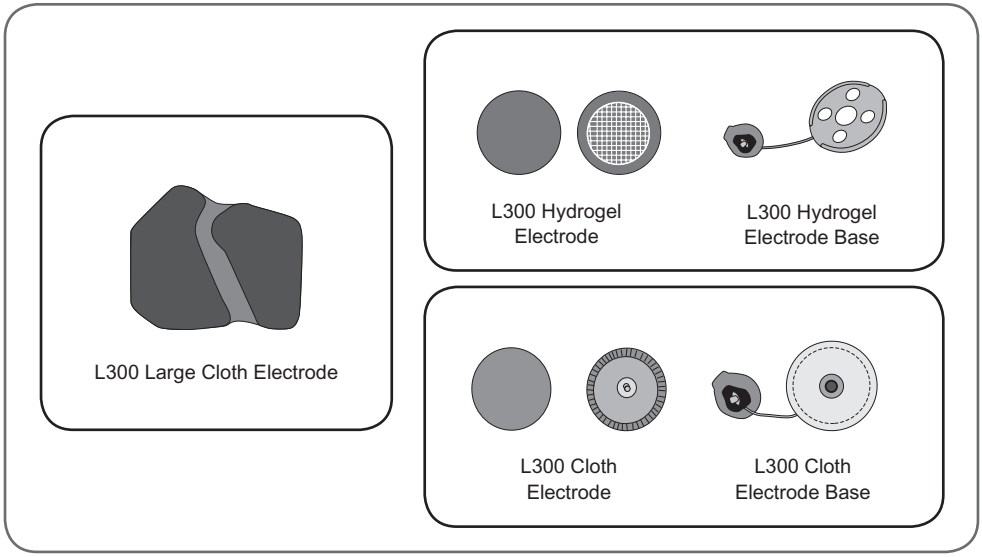


Figure 6-1: L300 electrodes and bases.

Large Cloth Electrode

The L300 FS Cuff uses one large cloth electrode. The large cloth electrode snaps to the L300 FS Cuff plug holes. No electrode base is required.

Wet the large cloth electrode before use. After every three to four hours of use, remove and rewet the large cloth electrode. If the L300 FS Cuff is removed for more than one hour, wet the large cloth electrode again before use.

CAUTION: Replace the large cloth electrode every two weeks.

To rewet/replace the large cloth electrode:

1. Turn off the L300 Plus System, and remove the L300 FS Cuff.
2. Gently remove the large cloth electrode from the L300 FS Cuff. See Figure 6-2.

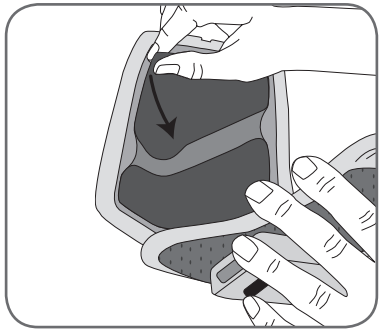


Figure 6-2: Removing the large cloth electrode.

CAUTION: Do not fold or twist the large cloth electrode.

3. Wet the entire large cloth electrode with water. See Figure 6-3.

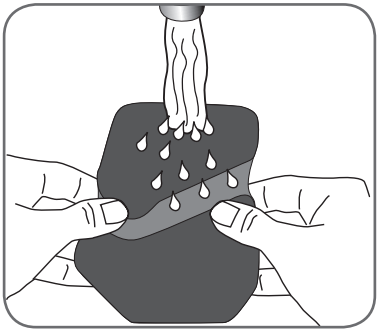


Figure 6-3: Wetting the large cloth electrode.

4. Remove excess water from the large cloth electrode. See Figure 6-4.

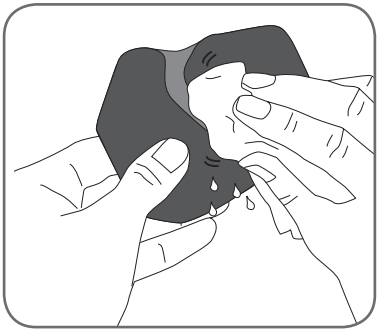


Figure 6-4: Blotting the large cloth electrode.

5. Align the orange and blue snaps on the large cloth electrode with the orange and blue plug holes on the L300 FS Cuff. See Figure 6-5.

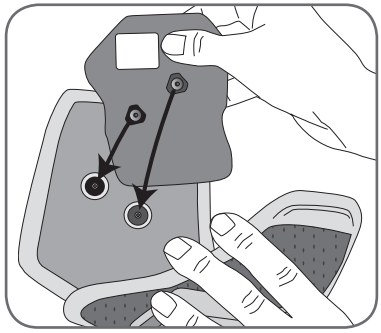


Figure 6-5: Aligning the large cloth electrode.

6. Press firmly to snap the large cloth electrode into the L300 FS Cuff. See Figure 6-6.

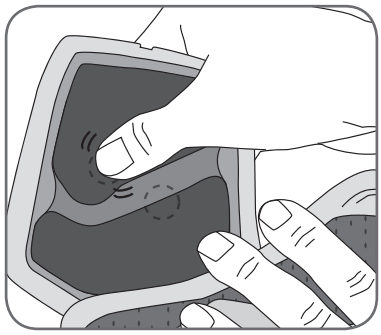


Figure 6-6: Snapping the large cloth electrode.

L300 Hydrogel Electrodes and Bases

The L300 FS Cuff uses two L300 hydrogel electrodes and two L300 hydrogel electrode bases. Your clinician will determine the best position for the L300 hydrogel electrode bases. Do not move the bases.

The L300 hydrogel electrodes adhere to the hydrogel electrode bases. The grid side of the hydrogel electrode faces the hydrogel electrode base. See Figure 6-7.

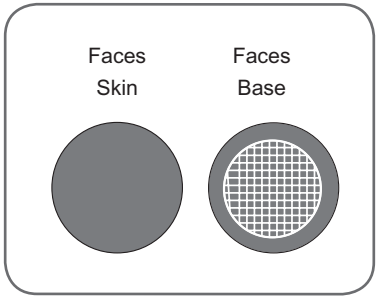


Figure 6-7: L300 hydrogel electrode, front and back.

CAUTION: Replace the electrodes every two weeks.

To replace the L300 hydrogel electrodes:

1. Turn off the L300 Plus System and remove the L300 FS Cuff.
2. Gently pull the L300 hydrogel electrodes from the bases. Be careful not to detach the bases from the L300 FS Cuff. See Figure 6-8.

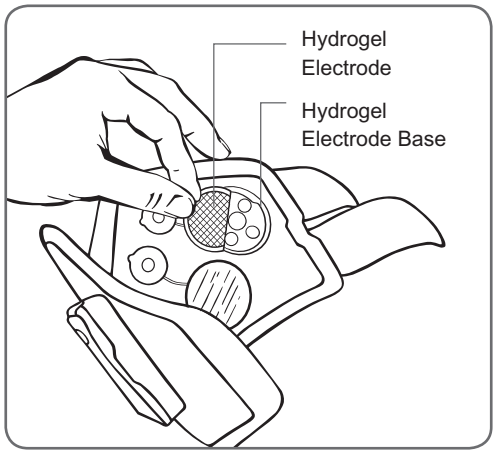


Figure 6-8: Removing the used L300 hydrogel electrodes.

3. If necessary, clean the bases with a damp cloth. Do not use a chemical-based cleaning substance.

4. Separate the new L300 hydrogel electrodes along the perforation. See Figure 6-9.

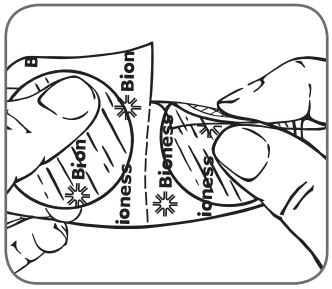


Figure 6-9: Separating the new L300 hydrogel electrodes.

5. Split the two-piece covers on each L300 hydrogel electrode and discard them. See Figure 6-10.

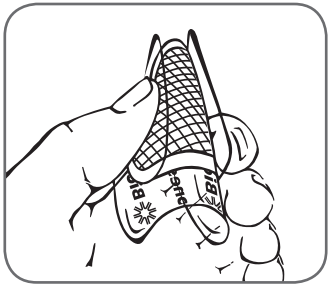


Figure 6-10: Splitting the two-piece covers on the L300 hydrogel electrodes.

6. Adhere the grid side of the L300 hydrogel electrodes to the L300 hydrogel electrode bases, and then press firmly. See Figure 6-11.

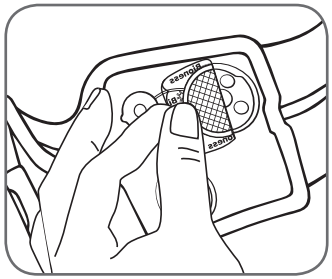


Figure 6-11: Adhering the L300 hydrogel electrodes to the bases.

7. Remove the covers from the L300 hydrogel electrodes. See Figure 6-12.

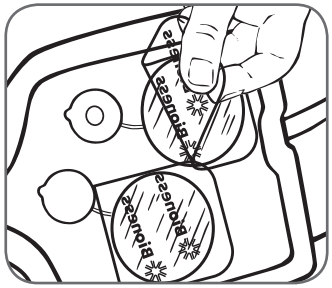


Figure 6-12: Removing the covers from the L300 hydrogel electrodes.

Note: Save the covers. Always reapply the covers between uses.

Note: If the electrode gel dries, rehydrate it with one to two drops of water.

L300 Cloth Electrodes and Bases

The L300 cloth electrodes are for people who opt to use them instead of the L300 hydrogel electrodes. They are also for people who have sensitivities to hydrogel electrodes or other known sensitivities (for example, allergy or skin sensitivity to tape/adhesive).

The L300 FS Cuff uses two L300 cloth electrodes and two L300 cloth electrode bases. Your clinician will determine the best position for the L300 cloth electrode bases. Do not move the bases.

The cloth electrodes snap to the cloth electrode bases. See Figure 6-13.

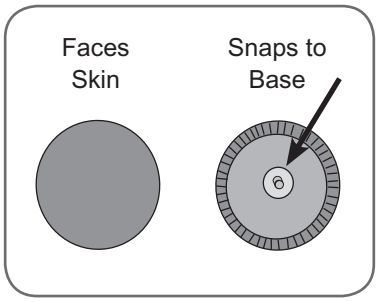


Figure 6-13: L300 cloth electrode, front (left) and back (right).

Wet the L300 cloth electrodes before use. Then remove and rewet the cloth electrodes after every three to four hours of use. If the L300 FS Cuff is removed for more than one hour, wet the cloth electrodes again before use.

CAUTION: Replace the electrodes every two weeks.

To rewet/replace the L300 cloth electrodes:

1. Turn off the L300 Plus System and remove the L300 FS Cuff.
2. Gently pull the L300 cloth electrodes from the bases. Be careful not to detach the bases from the L300 FS Cuff. See Figure 6-14.

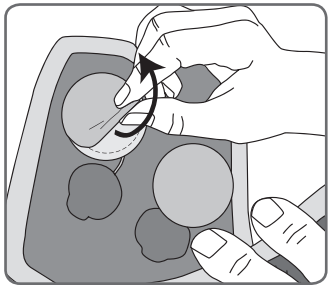


Figure 6-14: Removing the L300 cloth electrodes.

3. If necessary, clean the L300 cloth electrode bases with a damp cloth. Do not use a chemical-based cleaning substance.

4. Wet the L300 cloth electrodes with water until they are saturated. See Figure 6-15.

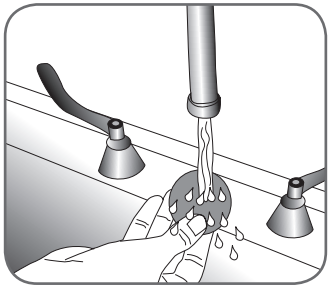


Figure 6-15: Wetting the L300 cloth electrodes.

5. With a soft cloth, gently wipe or blot excess water from the snap side of the cloth electrodes. See Figure 6-16.

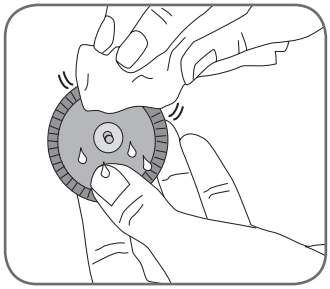


Figure 6-16: Blotting the snap side of the L300 cloth electrodes.

6. Snap the L300 cloth electrodes to the L300 cloth electrode bases. See Figure 6-17.

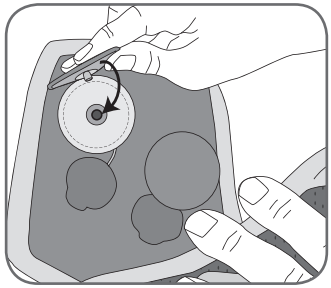


Figure 6-17: Snapping the L300 cloth electrodes to the cloth electrode bases.

Note: If the L300 cloth electrodes dry out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try rewetting the cloth electrodes.

CAUTION: Store cloth electrodes where they can air dry.

CAUTION: Only use electrodes provided by Bioness Inc.

Thigh Cloth Electrodes

The Thigh cloth electrodes deliver stimulation to the muscles in the upper leg. The Thigh FS Cuff uses two Thigh cloth electrodes. The large Thigh cloth electrode snaps to the Thigh FS Cuff top panel. The small Thigh cloth electrode snaps to the Thigh FS Cuff bottom panel. See Figure 6-18.

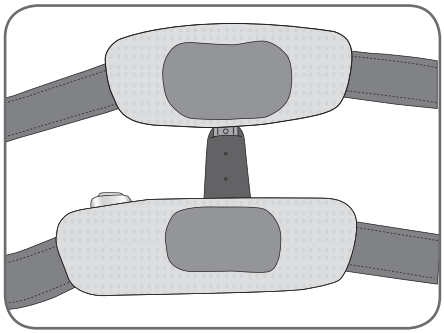


Figure 6-18: Thigh cloth electrodes on the Thigh FS Cuff.

CAUTION: Wet the cloth electrodes before use, and remove and rewet them after every three to four hours of use.

CAUTION: The electrodes are for single patient use.

The small Thigh cloth electrode has a marking around one of the snaps. Align the marking with the electrode marking ring on the Thigh FS Cuff bottom panel. See Figure 6-19.

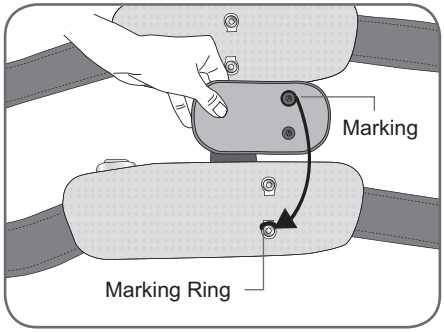


Figure 6-19: Aligning the small Thigh cloth electrode.

Wet the Thigh cloth electrodes before use. After every three to four hours of use, remove and rewet the Thigh cloth electrodes. If the Thigh FS Cuff is removed for more than one hour, wet the cloth electrodes again before use.

Note: If the Thigh cloth electrodes dry out, your response to the stimulation may change. If you need to adjust stimulation intensity more often than usual, try re-wetting the cloth electrodes.

Store the Thigh cloth electrodes where they can air dry.

CAUTION: Replace the electrodes every two weeks.

To rewet/replace the Thigh cloth electrodes:

1. Turn off the L300 Plus System and remove the Thigh FS Cuff.
2. Gently unsnap the Thigh cloth electrodes. See Figure 6-20.

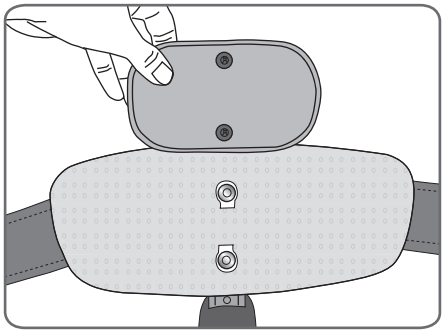


Figure 6-20: Unsnapping the Thigh cloth electrodes.

3. Wet the Thigh cloth electrodes with water until they are saturated. See Figure 6-21.

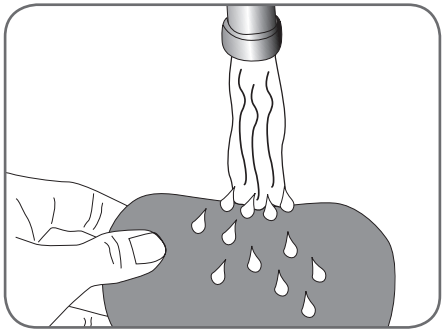


Figure 6-21: Wetting the Thigh cloth electrodes.

4. Gently squeeze the Thigh cloth electrodes together.
5. Blot excess water from the snap side of the Thigh cloth electrodes. See Figure 6-22.

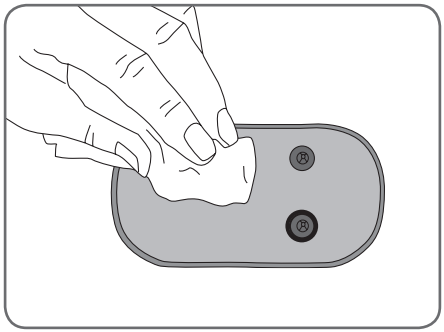


Figure 6-22: Blotting the snap side of the Thigh cloth electrodes.

6. Snap the Thigh cloth electrodes to the Thigh FS Cuff. See Figure 6-23.

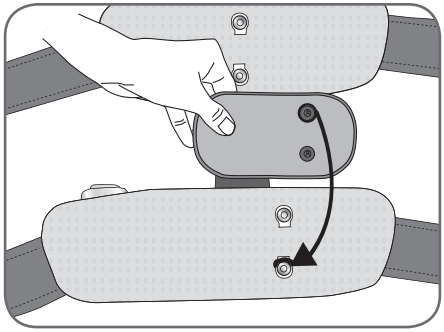


Figure 6-23: Snapping the Thigh cloth electrodes to the Thigh FS Cuff.

Thigh Electrode Marking Ring

The Thigh electrode marking ring marks the orientation of the small Thigh cloth electrode on the bottom panel of the Thigh FS Cuff. Align the marking on the small Thigh cloth electrode with the marking ring. See Figure 6-24.

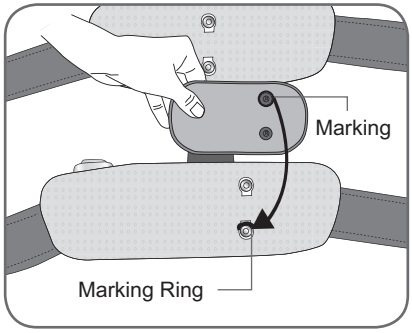


Figure 6-24: Aligning the small Thigh cloth electrode.

Attach replacement Thigh electrode marking rings to the same snap. See Figure 6-25.

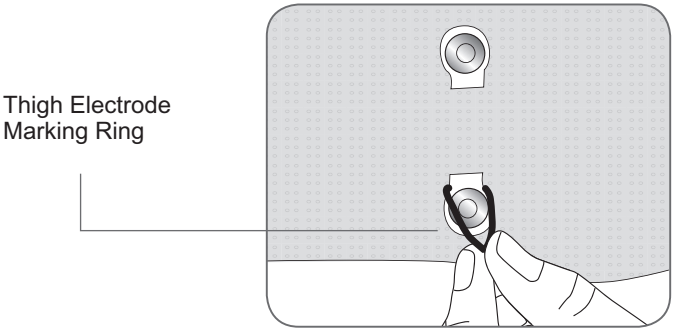


Figure 6-25: Replacing the Thigh electrode marking ring.

Cloth Electrode Mesh Bag

The cloth electrode mesh bag is for storing the L300 and Thigh cloth electrodes. See Figure 6-26.

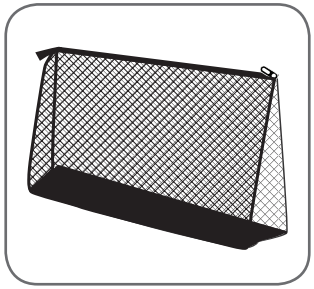


Figure 6-26: Cloth electrode mesh bag.

Thigh Elongation Bar Lock

The Thigh elongation bar lock prevents the elongation bar from sliding. See Figure 6-27.

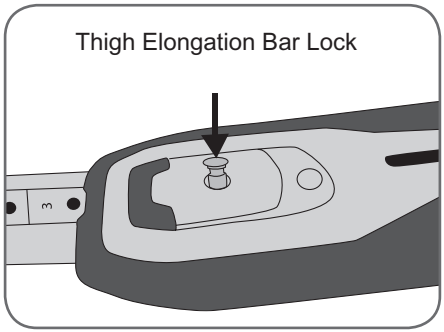


Figure 6-27: Thigh elongation bar lock.

Do not attempt to remove the Thigh elongation bar lock or to adjust the elongation bar. Contact your clinician if you think the elongation bar needs adjustment.

Control Unit Wrist Strap, Neck Strap, and Belt Pouch

The L300 Plus control unit wrist strap, neck strap, and belt pouch are for carrying the L300 Plus Control Unit. The wrist and neck straps loop through the top of the L300 Plus Control Unit. See Figure 6-28.

Figure 6-28: L300 Plus Control Unit accessories.

System Charger Set

The system charger set is for charging the L300 RF Stim Unit, Thigh RF Stim Unit, and L300 Plus Control Unit simultaneously. The system charger set includes a W cable, a charger, and four interchangeable blades for Australia, European Union, U.K., and U.S. voltages. See Figure 6-29.

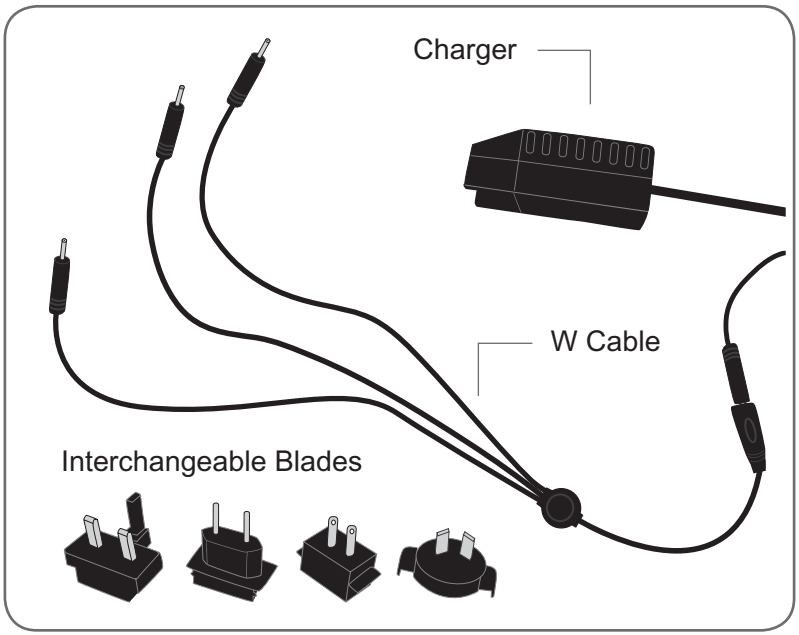


Figure 6-29: System charger set.

WARNING: Use only the charger included in your NESS L300 Plus System Kit or NESS L300 Plus System Upgrade Kit. Use of any other charger could damage the system.

Replacement Battery, Gait Sensor

The Intelli-Sense Gait Sensor battery may need to be replaced approximately every six months. See Figure 6-30. Battery replacement instructions can be found in the maintenance chapter of this guide.

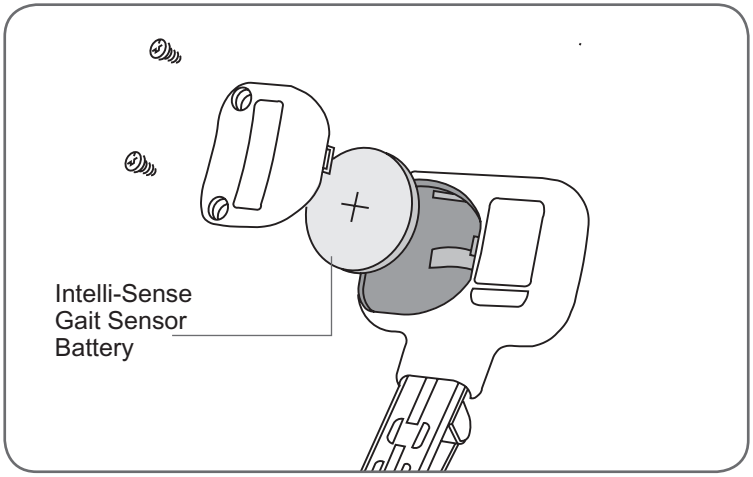


Figure 6-30: The Intelli-Sense Gait Sensor battery.

Gait Sensor Pads

The gait sensor pad stabilizes the Intelli-Sense Gait Sensor pressure sensor in the shoe. See Figure 6-31.

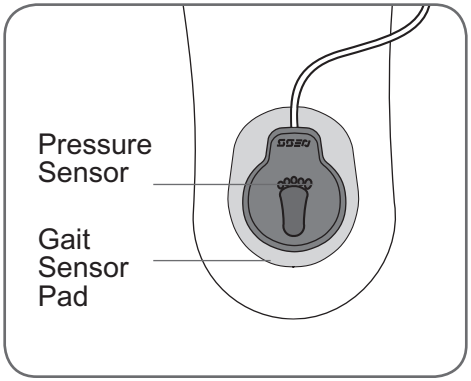


Figure 6-31: Placement of the gait sensor pad in the heel of a shoe.

One gait sensor pad is placed under the insole of the shoe of the affected leg. The pressure sensor is then placed on top of the gait sensor pad, and pressed down. (The adhesive side of the gait sensor pad faces down.) Finally, the insole of the shoe is lowered to cover both the pressure sensor and the gait sensor pad.

The location of the gait sensor pad is initially determined by your clinician.

Shoe Spacers

The shoe spacer is placed on the inner clamp of the Intelli-Sense Gait Sensor. See Figure 6-32.

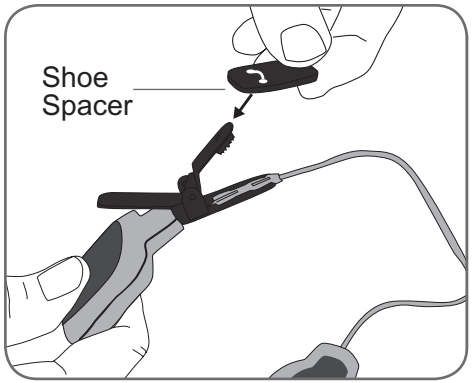


Figure 6-32: Attaching the shoe spacer to the Intelli-Sense Gait Sensor.

The shoe spacer:

- Stabilizes the Intelli-Sense Gait Sensor on the rim of the shoe.
- Protects the rim of the shoe from the clamp.

Setting Up the NESS L300 Plus System

Preparing the Skin

Before you put on the L300 and Thigh FS Cuffs, prepare your skin where the electrodes will touch.

To prepare your skin:

1. Clean the skin where the electrodes will touch with a wet washcloth. If any lotions are on the skin, clean the skin with soap and water. Rinse well.
2. If necessary, trim excess body hair from the area using an electric shaver or scissors. Do not use a razor. A razor can irritate the skin.
3. Check the skin for signs of irritation. If any irritation is present, stop using the NESS L300 Plus System. Contact your clinician and the Bioness Client Relations Department, Option 3. Wait for complete healing before using the NESS L300 Plus System.

Checking the Components

Check all components and accessories for signs of wear or damage. If any component is damaged, contact the **Bioness Client Relations Department at (800) 211-9136, Option 3.** If the electrodes are old, replace them.

Putting on the L300 FS Cuff

To put on the L300 FS Cuff:

1. Remove and wet the L300 cloth electrode(s), if appropriate.
2. Remove the covers on the hydrogel electrodes, if appropriate.
3. While seated, slightly straighten your leg. The outline of your kneecap should be clearly defined. Place your foot on a footrest, if necessary. See Figure 7-1

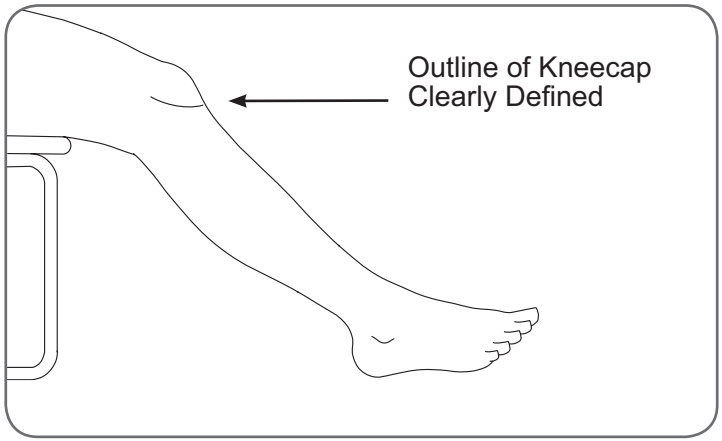


Figure 7-1: Recommended knee angle for putting on the L300 FS Cuff.

CAUTION: Turn off stimulation before putting on or taking off the L300 FS Cuff.

4. Grasp the front of the L300 FS Cuff by the cradle. Then tilt the bottom of the L300 FS Cuff up.
5. Slide the locator up your leg until it rests snugly and comfortably below your kneecap. See Figure 7-2.

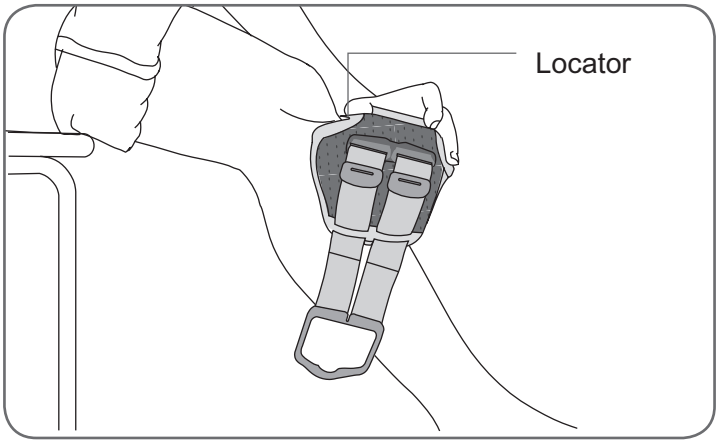


Figure 7-2: Aligning the L300 FS Cuff locator below the kneecap.

6. While holding the locator in place, lower the L300 FS Cuff until it rests flush against your leg. The L300 FS Cuff should gently grip your leg.
7. Grasp the handle of the L300 FS Cuff strap.
8. With your thumb on the cradle, fasten the L300 FS Cuff strap handle around the cradle. See Figure 7-3.

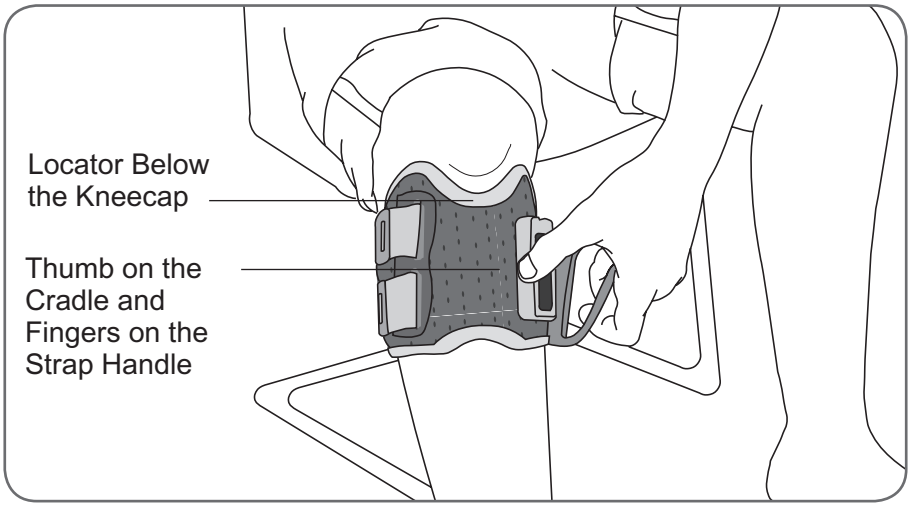


Figure 7-3: Fastening the L300 FS Cuff strap.

9. Make sure the L300 FS Cuff is correctly positioned. The locator should rest below the kneecap. The RF Stim Unit should face the inside of the leg. See Figure 7-4.

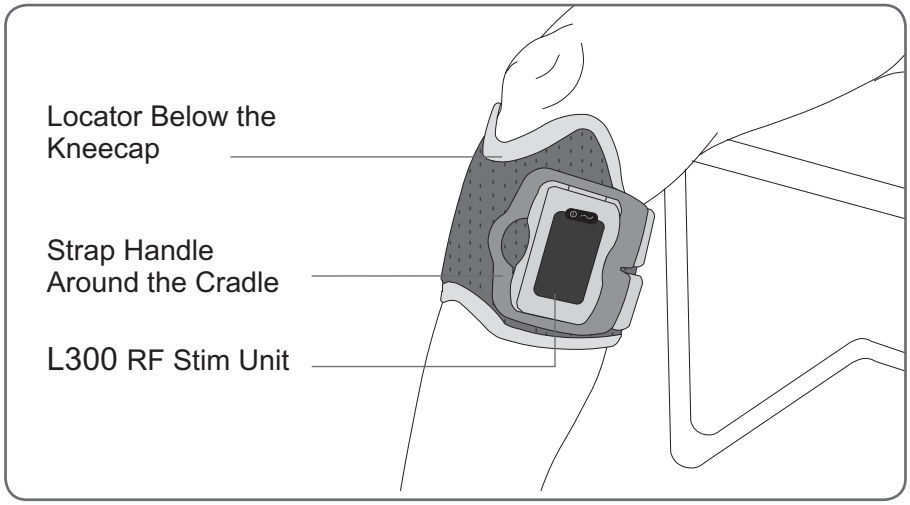


Figure 7-4: The L300 FS Cuff correctly positioned on the right leg.

Testing the Position of the L300 FS Cuff

To test the position of the L300 FS Cuff:

1. Place the L300 Plus Control Unit in standby mode.
2. Press the L300 RF Stim Unit selection button. The arrow next to the L300 RF Stim Unit indicator will light GREEN to confirm the selection.
3. Press and hold the stimulation test button. The L300 RF Stim Unit will stimulate until the stimulation test button is released.

If the L300 FS Cuff is not positioned correctly:

1. Turn off the L300 Plus System.
2. Unhook the L300 FS Cuff strap handle from the cradle.
3. Slowly lift the L300 FS Cuff away from the skin.
4. If appropriate, gently peel the L300 hydrogel electrodes from the skin. Then make sure the L300 hydrogel electrodes are adhered correctly to the bases.
5. Repeat the steps for putting on the L300 FS Cuff.
6. Retest the position of the L300 FS Cuff.

CAUTION: Remove the L300 FS Cuff from the skin every 3 to 4 hours for 15 minutes to allow the skin to breathe.

Putting on the Thigh FS Cuff

To put on the Thigh FS Cuff:

1. Remove and wet the Thigh cloth electrodes.
2. Sit in a stable position on the edge of a chair.
3. Place the Thigh FS Cuff locator on the midline of the thigh, approximately three finger widths from the knee. See Figure 7-5.

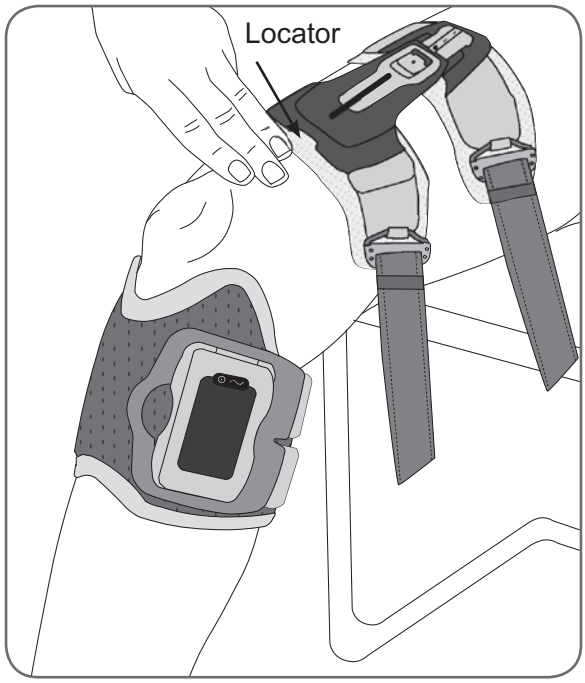


Figure 7-5: Thigh FS Cuff locator correctly positioned on the quadriceps.

4. Center the elongation bar on the midline of the thigh. See Figure 7-6.

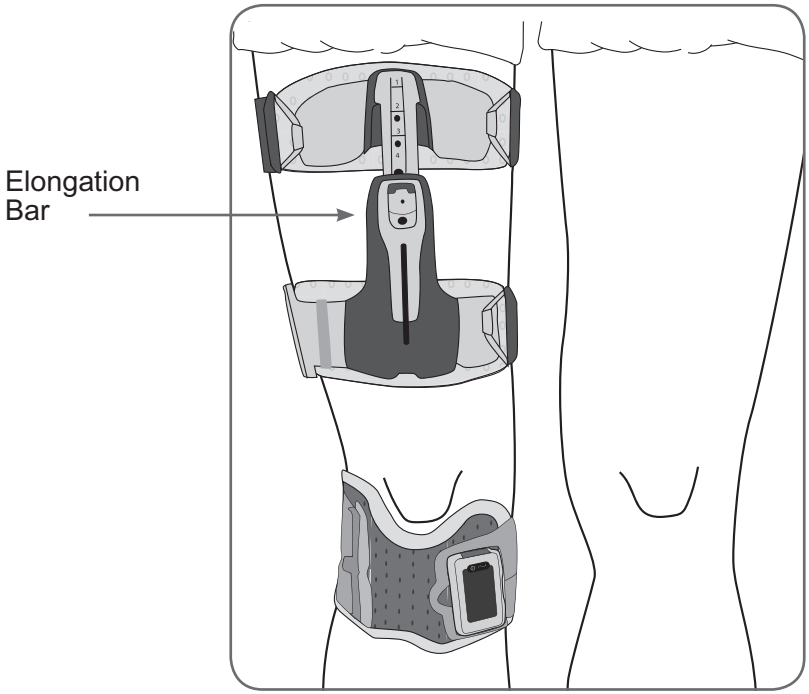


Figure 7-6: Thigh FS Cuff correctly positioned on the quadriceps.

5. Fasten the straps.

CAUTION: Turn off stimulation before putting on or taking off the Thigh FS Cuff.

Testing the Position of the Thigh FS Cuff

To test the position of the Thigh FS Cuff:

1. Place the L300 Plus Control Unit in standby mode.
2. Press the Thigh RF Stim Unit selection button. The arrow next to the Thigh RF Stim Unit indicator will light GREEN to confirm the selection.
3. Press and hold the stimulation test button. The Thigh RF Stim Unit will stimulate until the stimulation test button is released.

If the Thigh FS Cuff is not positioned correctly:

1. Turn off the L300 Plus System.
2. Loosen the Thigh FS Cuff.
3. Slowly lift the Thigh FS Cuff from the skin.
4. Make sure the Thigh cloth electrodes are wet and attached correctly.
5. Repeat the steps for putting on the Thigh FS Cuff.
6. Retest the position of the Thigh FS Cuff.

Note: Do not rotate (slide) the Thigh FS Cuff on the leg while it is fastened. Rotating the Thigh FS Cuff while it is fastened could loosen or damage the Thigh cloth electrodes.

CAUTION: Remove the Thigh FS Cuff from the skin every 3 to 4 hours for 15 minutes to allow the skin to breathe.

Placing the Intelli-Sense Gait Sensor in the Shoe

The Intelli-Sense Gait Sensor is used when walking in gait mode. Make sure it is placed in your shoe before selecting gait mode.

To position the pressure sensor:

1. Lift the insole of the shoe, and attach a gait sensor pad under the insole, at the heel of the shoe. Make sure the gait sensor pad is in the same location as initially fitted by your clinician. See Figure 7-7.

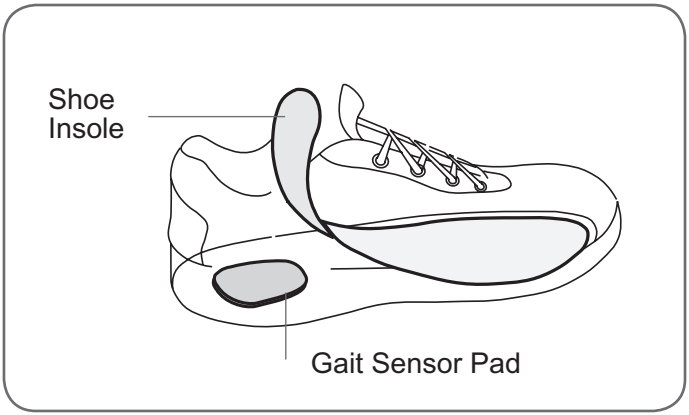


Figure 7-7: Lifting the insole and attaching a gait sensor pad.

CAUTION: Do not use the Intelli-Sense Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.

Note: If your shoe does not have a detachable insole, place the pressure sensor on top of the insole. Then, place a generic (one layer versus two) insole over it. Generic insoles can be purchased from drugstores, shoe stores, or Bioness. Contact the **Bioness Client Relations Department at (800) 211-9136, Option 2.**

2. Point the wire of the pressure sensor toward the toe of the shoe. Then press the pressure sensor to the gait sensor pad. See Figure 7-8.

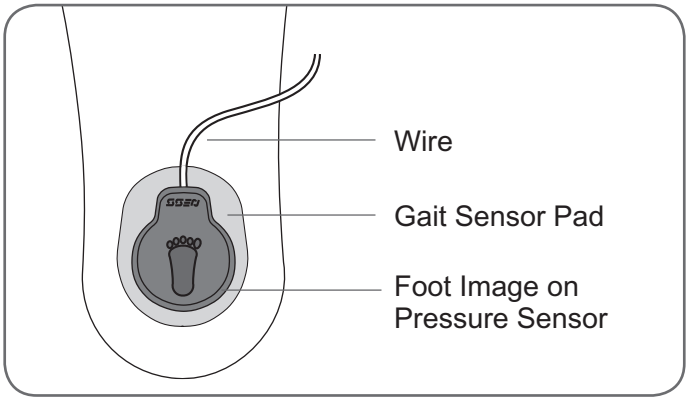


Figure 7-8: Positioning the pressure sensor in the heel of the shoe

Note: Refer to the foot image on the pressure sensor for correct orientation.

CAUTION: The Intelli-Sense Gait Sensor has not been validated for use by individuals weighing more than 300 pounds (136 kilograms).

To position the transmitter:

1. Cover the inner clamp of the Intelli-Sense Gait Sensor with the shoe spacer. See Figure 7-9.

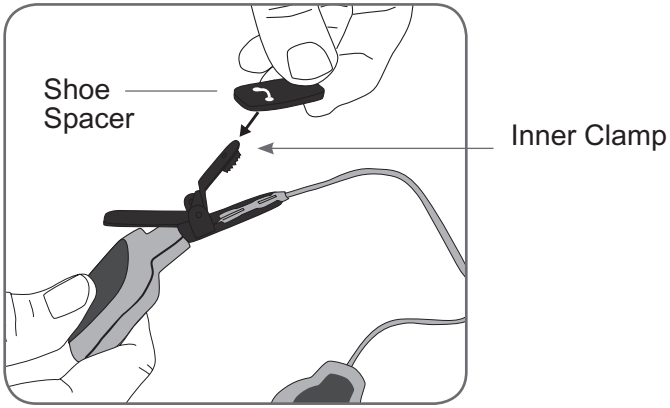


Figure 7-9: Attaching the shoe spacer.

2. Clamp the transmitter to the inner rim of the shoe. The NESS logo on the transmitter should face away from the ankle. See Figure 7-10.

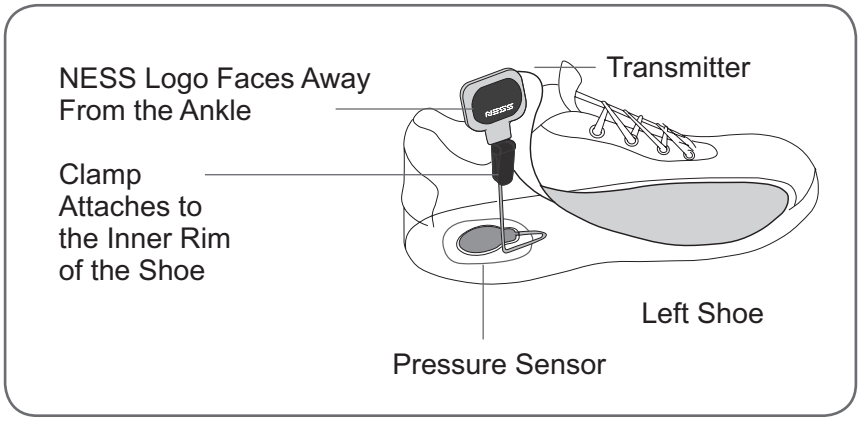


Figure 7-10: Clamping the transmitter to the inner rim of the shoe.

3. Lower the insole. Tuck any excess wire under the insole. See Figure 7-11.

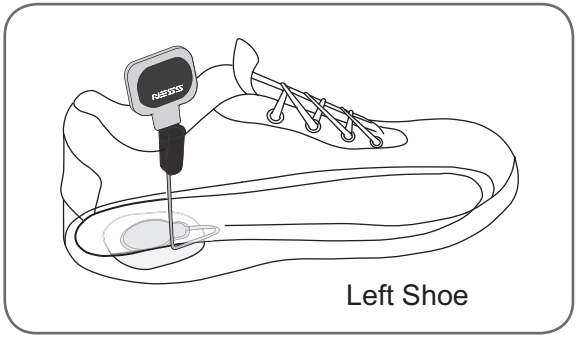


Figure 7-11: Intelli-Sense Gait Sensor correctly positioned.

Transferring the Intelli-Sense Gait Sensor to Another Shoe

To transfer the Intelli-Sense Gait Sensor to another shoe:

1. Turn off the NESS L300 Plus System.
2. Remove the Intelli-Sense Gait Sensor from the shoe.
3. Select another shoe.
4. Follow the steps for placing the Intelli-Sense Gait Sensor in the shoe. Be sure to place the gait sensor pad in the same location as determined by your clinician.

Using Multiple Intelli-Sense Gait Sensors

If you have more than one Intelli-Sense Gait Sensor, you can place each one in a different shoe, and then switch shoes.

Note: Be sure to register any new Intelli-Sense Gait Sensor to your L300 Plus System. See Chapter 10.

To switch shoes using multiple Intelli-Sense Gait Sensors:

1. Turn off the NESS L300 Plus System.
2. Switch shoes.
3. Turn on the NESS L300 Plus System.

Operating the NESS L300 Plus System

The NESS L300 Plus System is designed to operate as a complete system. The L300 and Thigh FS Cuffs both must be on and the system components close to each other to communicate wirelessly.

Turning On/Off the NESS L300 Plus System

To turn on the NESS L300 Plus System, press the on/off button on the L300 Plus Control Unit once. The system will start in standby mode. All display indicators will light up for a few seconds while the system performs a self-test. The on/off button will FLASH GREEN to indicate the system is on.

To turn off the L300 Plus System, press the on/off button once.

Testing the Position of the FS Cuffs

The stimulation test button is used to test the position of the FS Cuffs. Only one FS Cuff can be tested at a time.

L300 FS Cuff

To test the position of the L300 FS Cuff:

1. Place the L300 Plus Control Unit in standby mode.
2. Press the L300 RF Stim Unit selection button. The arrow next to the L300 RF Stim Unit indicator will light GREEN to confirm the selection.
3. Press and hold the stimulation test button. The L300 RF Stim Unit will stimulate until the stimulation test button is released.

Thigh FS Cuff

To test the position of the Thigh FS Cuff:

1. Press the Thigh RF Stim Unit selection button. The arrow next to the Thigh RF Stim Unit indicator will light GREEN to confirm the selection.
2. Press and hold the stimulation test button. The Thigh RF Stim Unit will stimulate until the stimulation test button is released.

Selecting an Operating Mode

Selecting Gait Mode

To select gait mode:

1. Turn on the L300 Plus System.
2. Press the mode button *briefly.*

The L300 Plus Control Unit will beep and the mode button will FLASH YELLOW SLOWLY (stimulation is off). When stimulation is on, the mode button will FLASH YELLOW RAPIDLY.

Selecting Training Mode

To select training mode:

1. Turn on the L300 Plus System.
2. Press and *hold* the mode button.

The L300 Plus Control Unit will beep, the mode button will FLASH YELLOW SLOWLY, and (“t” for training) will alternate with the intensity level in the digital display.

When stimulation is on, the mode button will FLASH YELLOW RAPIDLY .

Returning to Standby Mode

To return to standby mode from gait or training mode:

- Press the flashing mode button briefly.

The L300 Plus Control Unit will beep, and the mode button will stop flashing.

Adjusting Stimulation Intensity

When the L300 Plus Control Unit is turned on, the stimulation intensity level will be “5."

L300 FS Cuff

T**o adjust stimulation intensity for the L300 FS Cuff:**

1. Press the L300 RF Stim Unit selection button. The arrow next to the L300 RF Stim Unit indicator will light GREEN to confirm the selection. See Figure 8-1.

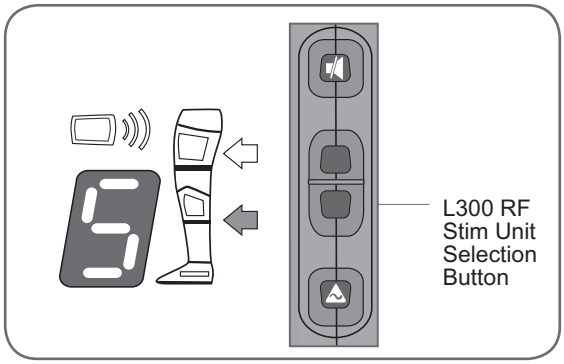


Figure 8-1: L300 RF Stim Unit selection.

2. Press the plus or minus intensity adjustment button on the L300 Plus Control Unit to change the intensity level.

The L300 Plus Control Unit will beep with each change in level. The new level will show in the digital display.

Note: An intensity level of “0” equals no stimulation.

Note: When the system is turned on, the default stimulation intensity level is restored.

Adjustment Guidelines

If your foot slightly drags or catches on the floor while walking, increase the stimulation intensity in the L300 FS Cuff to lift the foot higher.

If your foot rises too high while walking or if stimulation is unpleasant, decrease the stimulation intensity in the L300 FS Cuff. Be sure your foot does not drag or catch on the floor after decreasing the intensity level.

Consult your clinician if you have questions.

Thigh FS Cuff

To adjust stimulation intensity for the Thigh FS Cuff:

1. Press the Thigh RF Stim Unit selection button. The arrow next to the Thigh RF Stim Unit indicator will light GREEN to confirm the selection. See Figure 8-2.

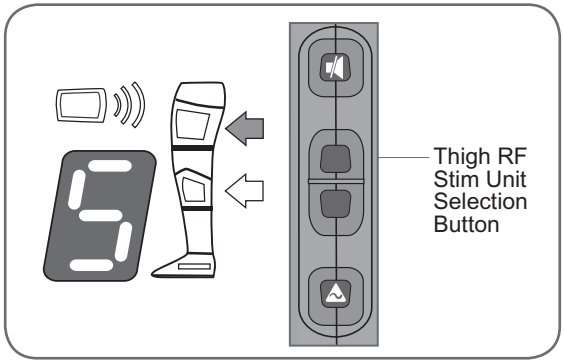


Figure 8-2: Thigh RF Stim Unit selection.

2. Press the plus or minus intensity adjustment button on the L300 Plus Control Unit to change the intensity level.

The L300 Plus Control Unit will beep with each change in level. The new level will show in the digital display.

Note: An intensity level of “0” equals no stimulation.

Note: When the system is turned on, the default stimulation intensity level is restored.

Turning on Audio Feedback During Stimulation

The mute button is used to turn on audio feedback when stimulation is on. Audio feedback can be turned on for one FS Cuff or both.

L300 FS Cuff

To turn on audio feedback during stimulation:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and hold the L300 RF Stim Unit selection button.
3. While holding the L300 RF Stim Unit selection button, press and hold the mute button for three seconds.

The L300 Plus Control Unit will emit an audio alert when stimulation is on.

To turn off audio feedback during stimulation:

- Press the mute button or the on/off button.

Thigh FS Cuff

To turn on audio feedback during stimulation:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and hold the Thigh RF Stim Unit selection button.
3. While holding the Thigh RF Stim Unit selection button, press and hold the mute button for three seconds.

The L300 Plus Control Unit will emit an audio alert when stimulation is on.

To turn off audio feedback during stimulation:

- Press the mute button or the FLASHING GREEN on/off button.

Muting/Un-Muting the L300 Plus Control Unit

To mute/un-mute the L300 Plus Control Unit:

- Press the mute button briefly.

Note: When the system is turned on, the default volume setting is restored.

Turning Off Audio/Visual Alerts

The NESS L300 Plus System is designed to be worn as a complete system in gait mode, with both the L300 FS Cuff and the Thigh FS Cuff on. In training mode, the L300 FS Cuff and the Thigh FS Cuff can be worn individually.

When only one FS Cuff is worn, the NESS L300 Plus System will emit a faulty electrode contact alert for the other FS Cuff. It will also emit an RF communication error alert for the other RF Stim Unit, if it is out of range. These alerts can be temporarily turned off.

L300 FS Cuff

To temporarily turn off the alerts:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and release the L300 RF Stim Unit selection button.
3. Press and hold the mute button for three seconds.

Thigh FS Cuff

To temporarily turn off the alerts:

1. Place the L300 Plus Control Unit in standby mode.
2. Press and release the Thigh RF Stim Unit selection button.
3. Press and hold the mute button for three seconds.

Note: When the system is turned on, the default settings are restored.

Maintenance and Cleaning

Daily Maintenance

When the NESS L300 Plus System is not in use:

1. If appropriate, reapply the covers to the hydrogel electrodes. Do not let the hydrogel dry out.
2. Store the cloth electrodes where they can air dry.
3. Allow the FS Cuffs to air dry.
4. Check each component for wear or damage.
5. Replace any components or electrodes that appear old, worn, or damaged.
6. Fully charge the L300 Plus Control Unit, Thigh RF Stim Unit, and L300 RF Stim Unit batteries.

Charging the Batteries

When a NESS L300 Plus System component has a low battery, the L300 Plus Control Unit will beep and the component indicator light will FLASH YELLOW. See Figure 9-1.

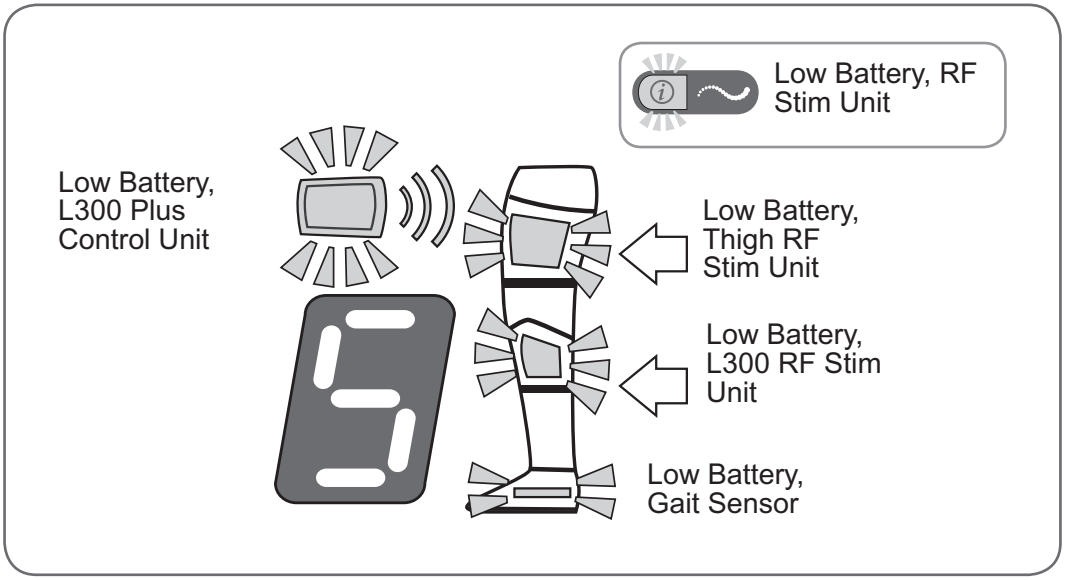

Low Battery, RF Stim Unit
Low Battery, L300 Plus Control Unit
Low Battery, Thigh RF Stim Unit
Low Battery, L300 RF Stim Unit
Low Battery, Gait Sensor

Figure 9-1: Low battery FLASHING YELLOW indicators.

When an RF Stim Unit battery charge level is low, the RF Stim Unit status light will also FLASH YELLOW. See inset in Figure 9-1.

When the Intelli-Sense Gait Sensor battery charge level is low, the L300 Plus Control Unit low-battery audio alert will become more persistent as the battery weakens.

To charge the batteries in the L300 Plus Control Unit, L300 RF Stim Unit, and Thigh RF Stim Unit:

1. Select an appropriate blade. See Figure 9-2. Then slide the blade into the charger.

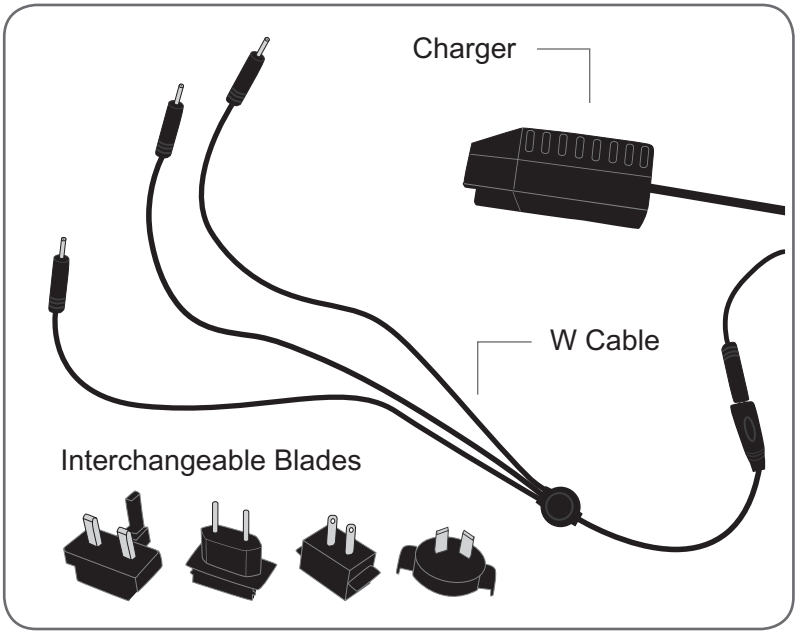


Figure 9-2: System charger set.

WARNING: Use only the charger included in your NESS L300 Plus System Kit or NESS L300 Plus System Upgrade Kit. Use of any other charger could damage the system.

2. Open the flexible covers over the charging ports. See Figure 9-3.

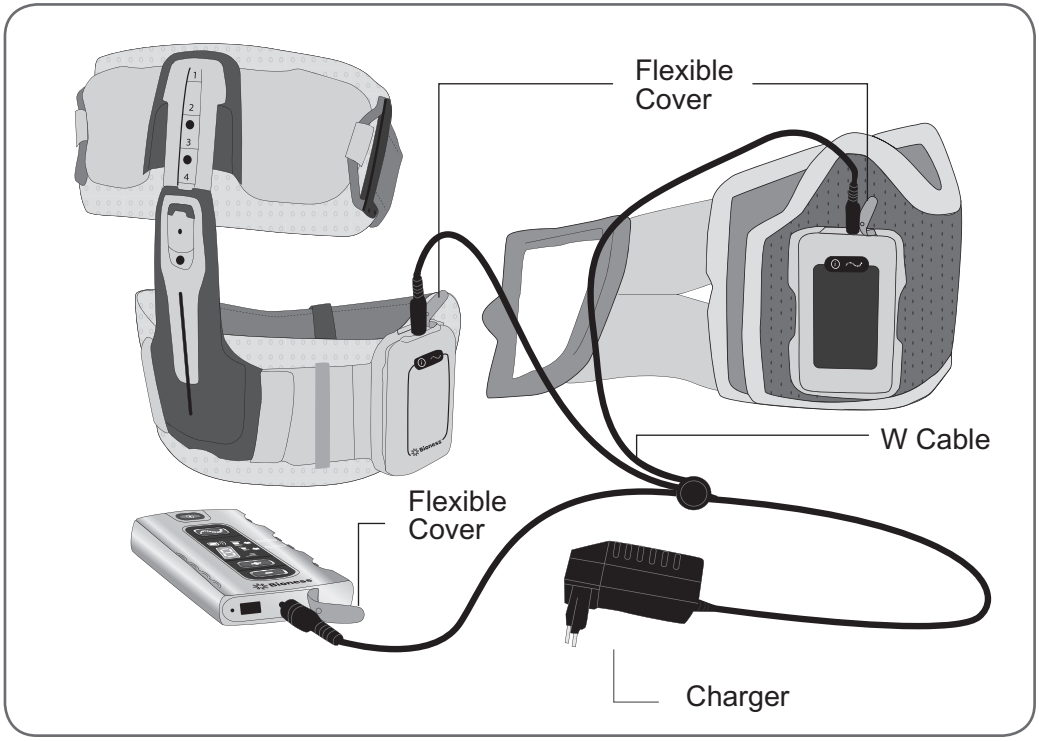


Figure 9-3: Charging setup.

3. Connect the W cable to the charging ports. See Figure 9-3
4. Plug the charger into a wall socket.
5. Verify that the rotating GREEN circle appears in the L300 Plus Control Unit digital display. See Table 9-1.
6. Verify that the status light on both RF Stim Units is ALTERNATELY FLASHING YELLOW and GREEN. See Table 9-2.

7. Allow the charging process to continue until:
    - A horizontal GREEN line appears in the L300 Plus Control Unit digital display. See Table 9-1.
    - The status light on both RF Stim Units is solid GREEN. See Table 9-2.

The charging process should last approximately three hours, but the L300 Plus Control Unit can take up to six hours to charge.

Note: Keep the L300 Plus Control Unit and RF Stim Units connected to the system charger set until ready for use.

Display	Description	Definition
	ROTATING GREEN Circle	L300 Plus Control Unit Charging
	Horizontal GREEN Line	L300 Plus Control Unit Fully Charged
	Letter "E" FLASHES while Charging	Charging Error

Table 9-1: L300 Plus Control Unit charging displays and definitions.

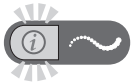
	Status Light ALTERNATELY FLASHES YELLOW and GREEN	Battery Charging
	Status Light SOLID GREEN	Battery Fully Charged

Table 9-2: RF Stim Unit charging displays and definitions.

Note: If the L300 Plus Control Unit battery is completely discharged, a “b” (for boot) will flash for a few seconds in the L300 Plus Control Unit digital display when charging is started.

Note: It is possible to charge the L300 Plus Control Unit and RF Stim Units separately, but Bioness recommends that they be charged at the same time.

CAUTION: The batteries must be charged before first use, daily, and after extended storage.

CAUTION: The Intelli-Sense Gait Sensor battery is not rechargeable.

CAUTION: Remove the L300 FS Cuff and Thigh FS Cuff before charging the RF Stim Unit batteries.

CAUTION: Do not use the RF Stim Units or the L300 Plus Control Unit while charging.

Battery Replacement

The battery in the Intelli-Sense Gait Sensor is not rechargeable. It may need to be replaced approximately every six months.

When the Intelli-Sense Gait Sensor battery charge level is low, the indicator on the L300 Plus Control Unit will begin to FLASH YELLOW. The alert will begin approximately two weeks before the Intelli-Sense Gait Sensor completely loses its charge. The L300 Plus Control Unit will also emit an audio alert.

To replace the Intelli-Sense Gait Sensor battery (Lithium coin cell, CR2430):

1. Using a Phillips screwdriver, unscrew the two screws from the battery cover. See Figure 9-4.

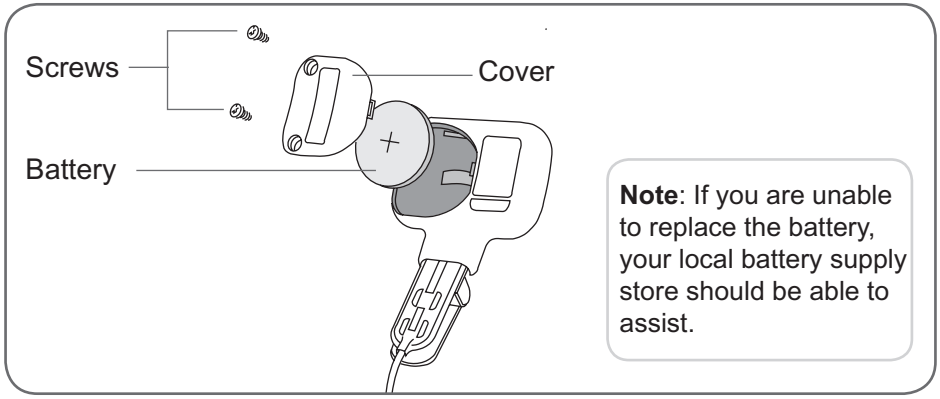

Screws
Cover
Battery
Note: If you are unable to replace the battery, your local battery supply store should be able to assist.

Figure 9-4: Replacing the Intelli-Sense Gait Sensor battery.

2. Slide the cover out.
3. Note the “+” orientation of the old battery.

Remove the old battery, and properly dispose of it according to your local environmental regulations.

4. Insert the new battery. The “+” should face outward.
5. Slide the cover back into place.
6. Tighten the screws.
7. Press the pressure sensor to activate the sensor.

CAUTION: Use only a battery supplied by Bioness.

The battery in the L300 Plus Control Unit is a rechargeable AAA NiMH battery. It should be replaced approximately every two years.

To replace the L300 Plus Control Unit battery (AAA NiMH 1.2 V):

1. Remove the screw from the battery cover on the back of the L300 Plus Control Unit. See Figure 9-5. (The screw is under a small label. Gently peel off the end of the label. Reapply the label after the battery is replaced.)
2. Remove the battery cover.
3. Note the "+/-" orientation of the old battery.

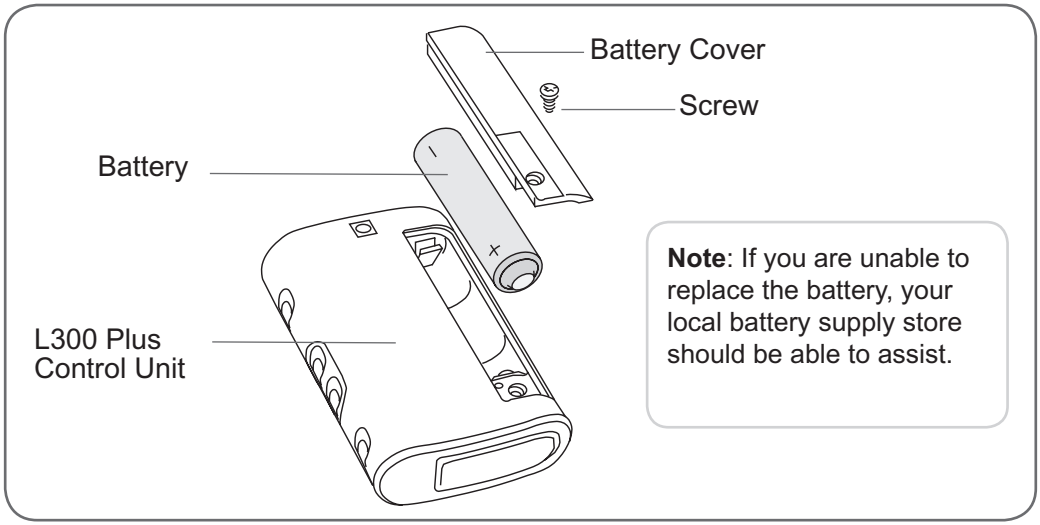

Battery Cover
Screw
Battery
L300 Plus
Control Unit
Note: If you are unable to replace the battery, your local battery supply store should be able to assist.

Figure 9-5: Replacing the L300 Plus Control Unit battery.

4. Insert the new rechargeable battery in the proper "+/-" orientation.
5. Slide the cover into place.

Remove the old battery, and properly dispose of it according to your local environmental regulations.

6. Tighten the screw.
7. Fully charge the new battery before use.

CAUTION: Use of a non-rechargeable AAA battery can damage the L300 Plus Control Unit.

CAUTION: Use only a battery supplied by Bioness.

The RF Stim Units have a rechargeable battery that can only be replaced by a Bioness authorized representative. If the battery needs to be replaced, contact the **Bioness Client Relations Department at (800) 211-9136, Option 3.**

Bases

Replace the L300 electrode bases if they appear worn or damaged.

To replace the L300 electrode bases:

1. Mark the position of the used L300 electrode bases on the L300 FS Cuff liner. See Figure 9-6.

Figure 9-6: Marking the position of the used L300 electrode bases.

2. Unsnap the L300 electrode bases from the plug holes. See Figure 9-7.

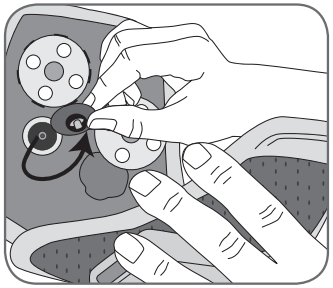


Figure 9-7: Unsnapping the L300 electrode bases.

3. Remove the used L300 electrode bases from the L300 FS Cuff. See Figure 9-8.

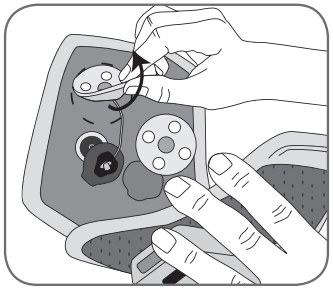


Figure 9-8: Removing the used L300 electrode bases.

4. Attach the new L300 electrode bases where the previous bases were attached. See Figure 9-9.

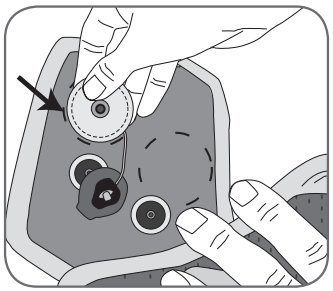


Figure 9-9. Attaching the new L300 electrode bases.

5. Snap the new L300 electrode bases to the L300 FS Cuff plug holes. See Figure 9-10.

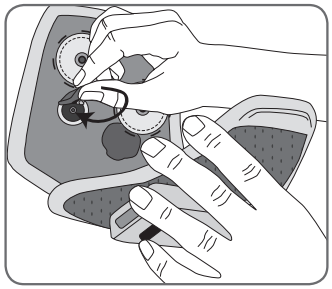


Figure 9-10: Snapping the L300 electrode bases to the L300 FS Cuff plug holes.

6. Cover the wires and snaps with wire concealers (not included), if desired. See Figure 9-11. Press on the wire concealers to attach them to the L300 FS Cuff liner.

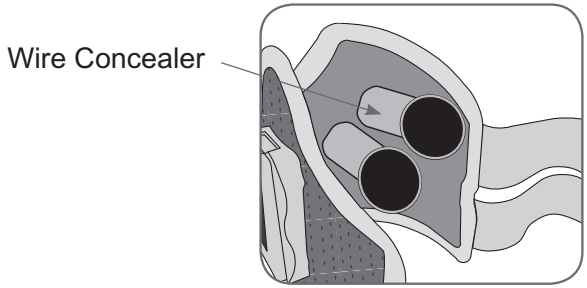


Figure 9-11: Wire concealers covering the L300 electrode base wires.

CAUTION: When replacing the L300 FS Cuff, have your clinician re-fit the L300 electrode bases.

L300 FS Cuff Strap

To replace the L300 FS Cuff strap:

1. Remove the used L300 FS Cuff strap from the L300 FS Cuff buckles and strap leads. See Figure 9-12.

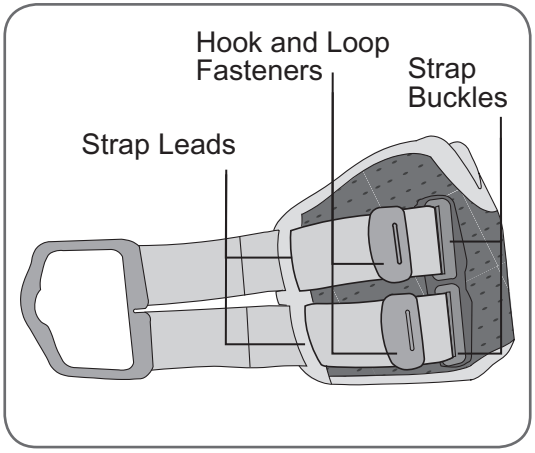


Figure 9-12: L300 FS Cuff strap attached to the L300 FS Cuff.

2. Slide the new L300 FS Cuff strap through the strap leads and buckles. Make sure the hook and loop fasteners face away from the L300 FS Cuff.
3. Press on the hook and loop fasteners to secure the strap.

Thigh Silicone Panels

To replace the Thigh silicone panels:

1. Unsnap and remove the Thigh cloth electrodes.

2. Gently detach the loops of the silicone panels from the hooks on the Thigh FS Cuff top and bottom panels. See Figure 9-13.

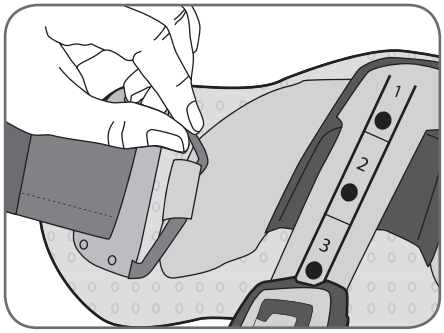


Figure 9-13: Unhooking the top silicone panel.

3. Slide the band on the bottom silicone panel over the Thigh RF Stim Unit. See Figure 9-14.

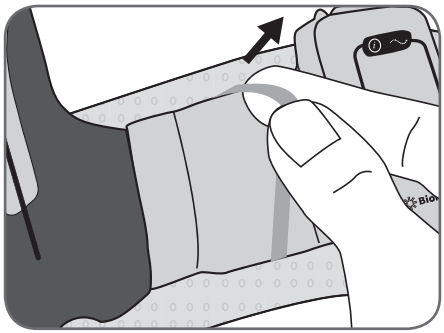


Figure 9-14: Sliding the band on the bottom silicone panel.

4. Gently pull the silicone panels away from the cloth electrode snaps. See Figure 9-15.

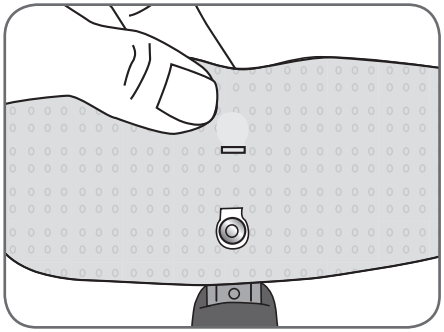


Figure 9-15: Pulling the silicone panels away from the electrode snaps.

5. Gently slide the new silicone panels around the electrode snaps.

6. Slide the band on the bottom silicone panel over the Thigh RF Stim Unit. See Figure 9-16.

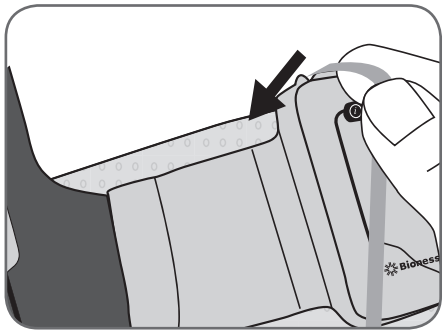


Figure 9-16: Sliding the band on the bottom silicone panel over the RF Stim Unit.

7. Gently hook the new silicone panels to the Thigh FS Cuff. See Figure 9-17.

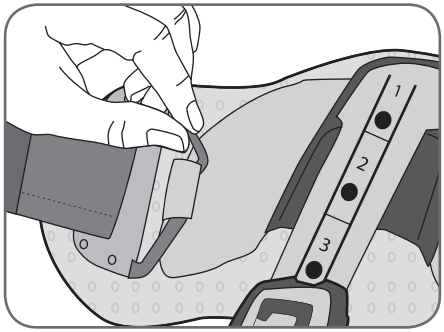


Figure 9-17: Hooking the new silicone panel to the Thigh FS Cuff.

Removing the L300 and Thigh RF Stim Units

The L300 and Thigh RF Stim Units should only be removed for maintenance and to clean the FS Cuffs.

To remove the RF Stim Units:

1. Turn off the L300 Plus System.
2. Pull the top of the RF Stim Unit away from the cradle. See Figure 9-18.

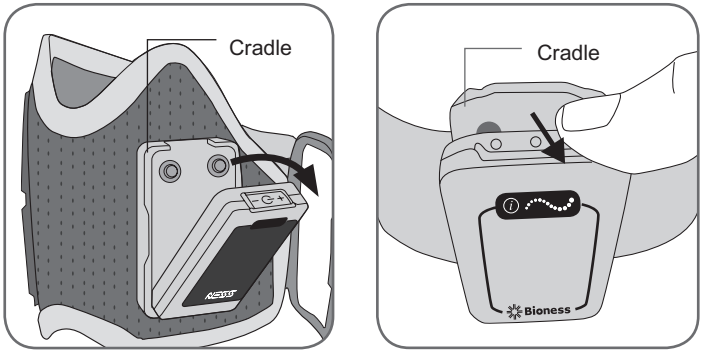


Figure 9-18: Removing the RF Stim Units.

Note: If the fit is too tight, open the flexible cover over the RF Stim Unit charging port for a better grasp.

3. Remove the bottom of the RF Stim Unit from the cradle.

To re-insert the RF Stim Unit:

1. Insert the bottom of the RF Stim Unit into the cradle. Then, gently push the top of the RF Stim Unit until it snaps into the cradle.

Cleaning the L300 Plus Components

All L300 Plus components may be cleaned by carefully wiping them with a damp cloth. The electrical components are not waterproof. **Do not immerse them in water.**

The L300 FS Cuff is the only component that can be immersed in water to clean.

To clean the L300 FS Cuff:

1. Remove the L300 RF Stim Unit and, if appropriate, the large cloth electrode.
2. If using the L300 hydrogel or cloth electrodes, gently remove the electrodes from the electrode bases. *Do not remove the electrode bases.* For hydrogel electrodes, replace the electrode covers.
3. Immerse the L300 FS Cuff for 30 minutes in lukewarm water and mild detergent. *Do not use a washing machine.*
4. Rinse the L300 FS Cuff thoroughly under running water.
5. Immerse the L300 FS Cuff for an additional 15 minutes in clean, lukewarm water.
6. Rinse the L300 FS Cuff again under running water.
7. Gently blot excess moisture from the L300 FS Cuff with a towel. Do not wring the L300 FS Cuff. Lay the L300 FS Cuff flat in the shade to dry. *(Do not hang dry.)* Drying time will vary from 4 to 12 hours depending on temperature and humidity. For faster drying, place the L300 FS Cuff in front of a circulating *cold-air* fan. *Do not use a hot-air dryer or other heat source to dry.*
8. When the L300 FS Cuff is completely dry, insert the L300 RF Stim Unit and attach the electrode(s).

Disinfecting the L300 Plus Components

All NESS L300 Plus System Kit components excluding the L300 FS Cuff and the Thigh FS Cuff straps may be disinfected using CaviWipes™ (Metrex, Orange, CA) per the manufacturer's instructions. Metrex products are sold through authorized dealers worldwide. If you have difficulty locating Metrex CaviWipes, please call the **Bioness Client Relations Department at (800) 211-9136, Option 3.**

To disinfect the L300 Plus System components:

1. Clean the surface that faces the skin with a wet CaviWipes disinfection wipe.

Note: Read the manufacturer's instructions for use, and follow standard precautions for personal protection as appropriate.

2. Using one or more new CaviWipes, wipe the surface again, thoroughly, for 3 minutes. The surface should be visibly wet.

Electronic Registration

The NESS L300 Plus System components must be electronically registered to each other to communicate wirelessly. The components in your L300 Plus System Kit are registered.

If you have an L300 Plus System Upgrade Kit, bring your upgrade kit and your L300 Foot Drop System to your first fitting session. Your clinician will register your NESS L300 Plus System at your first fitting session.

This section describes the steps to register a replacement L300 Plus Control Unit, Thigh RF Stim Unit, L300 RF Stim Unit, or Intelli-Sense Gait Sensor. If you have any questions, please call the Bioness Client Relations Department, Option 3.

Note: Components can only be *successfully* registered once. Additional attempts will generate an error indication.

Setup:

1. Place the components you are registering close together on a table but not touching. See Figure 10-1.

Figure 10-1: Registration setup.

2. Make certain no other L300 Plus components are within 30 feet of the components you are registering.

3. Connect the components to the system charger set.

To register a replacement L300 Plus Control Unit or RF Stim Unit:

1. Turn off the L300 Plus System.
2. Simultaneously press and hold for three seconds the mode and minus buttons. The L300 Plus Control Unit will beep when registration begins.
3. The L300 Plus Control Unit digital display will show two alternating GREEN arches while registration is in process. See Figure 10-2.

Figure 10-2: Registration digital displays.

4. When registration is complete, (“C” for complete) will appear in the digital display and the L300 Plus Control Unit indicator will turn GREEN for a few seconds. See Figure 10-2. The L300 Plus Control Unit will beep.

Note: If (“E” for error) appears in the digital display, an error has occurred. Repeat steps 2 though 4.

5. After registration is complete, turn on your NESS L300 Plus System. If the replacement component is registered, the L300 and Thigh RF Stim Units will turn on. If you see an RF communication failure indication, then repeat the registration procedure.

6. Locate the System ID Number for the NESS L300 Plus System (for example, A334). The System ID Number can be found on the back label of the existing NESS L300 Plus System components.
7. Write the System ID Number on the blank label on the back of the replacement L300 Plus component. See Figure 10-3.

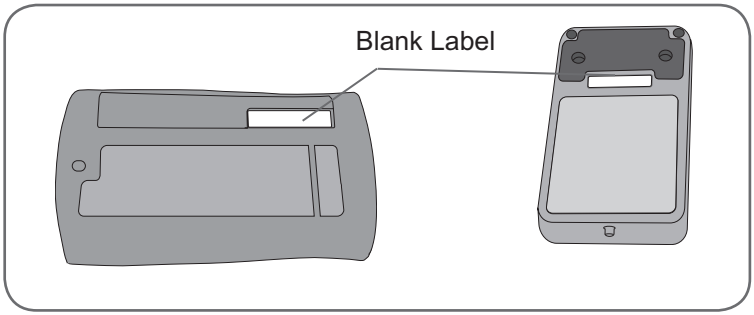


Figure 10-3: L300 Plus Control Unit (left) and RF Stim Unit (right).

CAUTION: Do not turn on the L300 Plus Control Unit if the L300 and Thigh RF Stim Units are not in their cradles.

To register a replacement/additional Intelli-Sense Gait Sensor:

Note: Read steps 1–4 before starting.

1. Turn off the L300 Plus System.
2. Simultaneously press and hold for three seconds the mode and minus buttons on the L300 Plus Control Unit. The L300 Plus Control Unit will beep when registration begins.
3. The L300 Plus Control Unit digital display will show two ALTERNATING GREEN arches while registration is in process.
4. **Within 15 seconds of initiating the registration procedure,** repeatedly press and release the pressure sensor.
5. When registration is complete, (“C” for complete) will appear in the digital display, the Intelli-Sense Gait Sensor indicator will turn GREEN for a few seconds, and the L300 Plus Control Unit will beep. If registration fails, then repeat the procedure.

Note: If (“E” for error) appears in the digital display, an error has occurred. Repeat the registration procedure. ("E" also can mean that the registration procedure was successful on a prior attempt and not noticed.)

6. After registration is complete, turn on the NESS L300 Plus System and select gait mode. Press and release the Intelli-Sense Gait Sensor pressure sensor. If the new Intelli-Sense Gait Sensor is registered, the mode button will FLASH YELLOW rapidly for four seconds.

7. Locate the System ID Number for the NESS L300 Plus System (for example, A334). The System ID Number can be found on the back label of the existing NESS L300 Plus System components. The System ID Number identifies which NESS L300 Plus System the replacement/additional Intelli-Sense Gait Sensor is registered to. The System ID Number on each component of a NESS L300 Plus System must match.
8. Write the number on the small label on the back of the new Intelli-Sense Gait Sensor. See Figure 10-4.

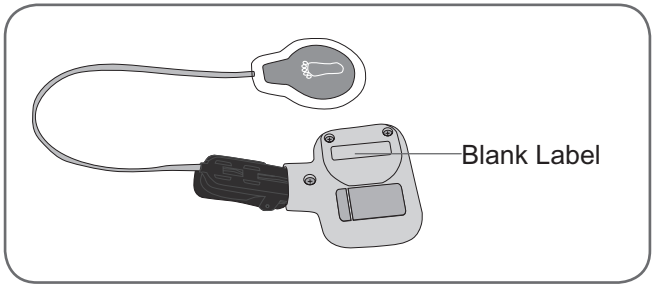


Figure 10-4: Intelli-Sense Gait Sensor.

Troubleshooting

If you have any questions or concerns, please call the **Bioness Client Relations Department at (800) 211-9136, Option 3.**

When charging the NESS L300 Plus System, how will I know when the batteries are fully charged?

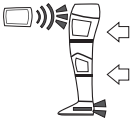
- When the L300 Plus Control Unit is fully charged, a GREEN horizontal line will appear in the L300 Plus Control Unit digital display.
- When the L300 and Thigh RF Stim Units are fully charged, the status light on the L300 and Thigh RF Stim Units will be SOLID GREEN.
- Charging takes approximately three hours, and it can take as long as six hours for the L300 Plus Control Unit to charge.
- After the components are fully charged, keep them connected to the system charger set until ready to use.

If I charge the NESS L300 Plus System every day, will I harm the batteries?

- No. Daily charging will not affect the lifespan or functionality of the batteries. Daily charging is recommended.

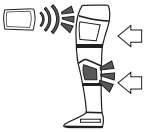
While charging, ("E") appears in the digital display.

- An error occurred while charging. Reconnect the system charger set. If the problem persists, contact the Bioness Client Relations Department, Option 3.



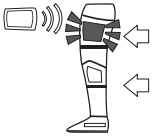
Stimulation works in training mode but not in gait mode. When I turn on gait mode I hear a beep. The Intelli-Sense Gait Sensor indicator and the RF communication indicator on the L300 Plus Control Unit ALTERNATELY FLASH RED.

- The Intelli-Sense Gait Sensor and the RF Stim Units are not communicating. The Intelli-Sense Gait Sensor is probably asleep. Press on the pressure sensor. If this does not resolve the problem, the Intelli-Sense Gait Sensor battery may be depleted or the sensor may be faulty. If no wire damage is apparent, replace the battery and try again.



When I turn on the L300 Plus Control Unit, it beeps and an RF Stim Unit indicator (L300 or Thigh) and the RF communication indicator ALTERNATELY FLASH RED. The indicators on the RF Stim Unit are not lit.

- The RF Stim Unit battery is likely discharged, preventing the L300 Plus Control Unit and RF Stim Unit from communicating. Turn off the L300 Plus Control Unit, remove the L300 and the Thigh FS Cuffs, and charge the NESS L300 Plus System fully. Then, disconnect the system charger set, put on the L300 and Thigh FS Cuffs, and turn on the NESS L300 Plus System. The L300 Plus Control Unit on/off button and the status light on the RF Stim Unit should FLASH GREEN. Communication should be restored.



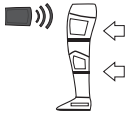
I hear a beep and an RF Stim Unit indicator (L300 or Thigh) on the L300 Plus Control Unit FLASHES RED.

- If you feel stimulation but the intensity level seems weaker than usual and movement (ankle and/or knee) is unsatisfactory, electrode contact may be compromised.
    - Turn off the L300 Plus System and remove the L300 and Thigh FS Cuffs.
    - Thoroughly cleanse the skin.
    - If appropriate, remove and replace the L300 hydrogel electrodes. Press firmly on the new hydrogel electrodes until they are securely attached to the hydrogel electrode bases. Then, remove the covers.
    - Remove the cloth electrodes and rewet them until they are saturated. Gently squeeze them together to remove excess water, blot the side with the snap, and replace them on the FS Cuff(s).
    - Replace the electrodes every two weeks.
- If you do not feel stimulation:
    - Turn off the L300 Plus System, and remove the L300 and Thigh FS Cuffs.
    - If appropriate, make sure the L300 hydrogel electrode covers have been removed.
    - Remove and rewet the cloth electrodes.

- Make sure the L300 and Thigh RF Stim Units are properly snapped into the cradles on the L300 and Thigh FS Cuffs. Press firmly near the upper edges of the L300 and Thigh RF Stim Units until they are flush with the cradles.
- Make sure the L300 hydrogel electrode bases (or L300 cloth electrode bases) are snapped into the plug holes of the L300 FS Cuff.
- Make sure the Thigh FS Cuff cloth electrodes are snapped securely to the Thigh FS Cuff. Check all snaps.
- Make sure neither the electrodes nor the electrode bases are frayed, peeling, damaged, or falling off the L300 and Thigh FS Cuffs.
- Replace any worn or damaged electrodes or L300 electrode bases.

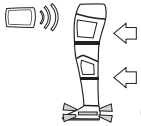
How will I know when the Intelli-Sense Gait Sensor battery charge level is low?

- An Intelli-Sense Gait Sensor battery will last for approximately six months, and then it will need to be replaced. When the Intelli-Sense Gait Sensor battery charge level is low, the Intelli-Sense Gait Sensor indicator on the L300 Plus Control Unit will FLASH YELLOW and the L300 Plus Control Unit will emit an audio alert. The audio alert will become more persistent as the battery weakens.



One of the component indicators is SOLID RED and the L300 Plus Control Unit beeps.

- The respective component is malfunctioning. Turn off the L300 Plus Control Unit and then turn it back on. If the problem persists, stop using the NESS L300 Plus System and contact Bioness.



One of the component indicators is FLASHING YELLOW.

- The respective component battery charge level is low. Charge or replace the battery.

My ankle and/or knee is not moving satisfactorily, and the NESS L300 Plus System is not indicating any errors.

- Turn off the L300 Plus Control Unit and reposition the L300 and/or Thigh FS Cuff. Test the position of the L300 and/or Thigh FS Cuff using the stimulation test button. Make sure the L300 FS Cuff strap and the Thigh FS Cuff straps are snug.

Stimulation is inconsistent when I am walking, but the NESS L300 Plus System is not indicating any errors.

- Stop walking and shift your weight from side to side. If the problem persists, check for proper placement of the Intelli-Sense Gait Sensor pressure sensor. Reposition the pressure sensor slightly forward in your shoe, or loosen your shoelace if it is tight. Also, check the Intelli-Sense Gait Sensor wires for wear or fraying. Check the transmitter and pressure sensor for damage.

My skin is irritated or has a skin reaction where the electrodes and the L300 and/or Thigh FS Cuffs touch.

- Stop using the NESS L300 Plus System immediately and contact your clinician or dermatologist, and the **Bioness Client Relations Department at (800) 211-9136, Option 3.** Resume use only when the skin is completely healed. Ask your clinician or dermatologist for a skin conditioning protocol.

I received a replacement component and was told I need to "register" it. Why is registration important and how do I register a component?

- A replacement L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, or Intelli-Sense Gait Sensor needs to be electronically registered to the other components in the NESS L300 Plus System to communicate wirelessly. For instructions on how to register a replacement component, see Chapter 10.

I tried the registration procedure and saw a immediately, but I never saw the alternating arches in the digital display. The replacement component is not working.

- Clinician mode (for use by clinicians only) may have been started instead of the registration process. Turn off the L300 Plus Control Unit, and press the minus and mode buttons to restart the registration process.

The L300 Plus Control Unit or one of the RF Stim Units does not light up when turned on.

- The NESS L300 Plus System needs to be charged. Charge the system. If the problem persists, contact the Bioness Client Relations Department, Option 3.

After I fully charged the NESS L300 Plus System, I disconnected the system charger set and then immediately reconnected it. The charging indications appeared again on the L300 Plus Control Unit and the L300 and Thigh RF Stim Units. Are the components still fully charged or do I need to repeat the charging process?

- If you recently charged your NESS L300 Plus System and the fully charged indications were displayed, your NESS L300 Plus System is still fully charged. You do not have to repeat the charging process.

Technical Specifications

L300 Plus Control Unit Specifications	
Classification	Internally powered, continuous operation
Operation Modes	Gait, Training, Clinician, and Standby
Battery Type	Rechargeable AAA NiMH 1.2 V, 900–1100 mAh
Controls	• On/Off illuminated button • Mode illuminated button to change operating modes • Intensity +/- buttons to fine-tune intensity level • Mute button to mute audio and visual alerts • RF Stim Unit selection buttons • Stimulation test button
Indications	• Seven status LEDs: L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, Intelli-Sense Gait Sensor, L300 RF Stim Unit and Thigh RF Stim Unit Arrow Indicators, and RF Communication • Numerical display designates relative stimulation intensity • Illuminated buttons designate system operating mode • “Beeps” for audio alerts
Carrying Options	In pocket, neck strap, wrist strap, or belt pouch
Dimensions	Length: 73 mm (2.9 in.); Width: 46 mm (1.8 in.); Height: 18 mm (0.7 in.)
Weight	45 grams (1.5 oz.)
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C (-13°F to +131°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Charging temperature: 5°C to 40°C (41°F to 104°F) • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

L300 RF Stim Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating Voltage	3.7 V
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 750 mAh
Indications	• Status (fault, battery, charging) and Stimulation LEDs • “Beeps” for audio alerts
Dimensions	• Length: 74 mm (2.9 in.) • Width: 43 mm (1.7 in.) • Height: 15 mm (0.6 in.)
Weight	50 grams (1.6 oz.)
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C (-13°F to +131°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Charging temperature: 5°C to 40°C (41°F to 104°F) • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric or Asymmetric
Intensity (Peak)	0–80 mA, 1-mA resolution (positive phase)
Maximum Intensity (rms)	13.2 mA (rms)
Max Voltage	120 V

	Symmetric			Asymmetric		
Positive Pulse Duration (µsec)	100	200	300	100	200	300
Negative Pulse Duration (µsec)	100	200	300	400	800	1200
Inter-Phase Interval (µsec)	50			0		
Total Pulse Duration (µsec)	250	450	650	500	1000	1500
Max Load	5000 ohm (Subject to max voltage limitation)					
Pulse Repetition Rate	20–45 Hz, 5-Hz resolution					
Gait Parameters						
Ramp Up	0–2 seconds, 0.1-second resolution					
Ramp Down	0–2 seconds, 0.1-second resolution					
Extend (%)	0–100% of stance time, 10% resolution					
Max. Duration of Stimulation	2–10 seconds, 1-second resolution					
Training Parameters						
On Time	4–20 seconds, 1-second resolution					
Off Time	4–60 seconds, 1-second resolution					
Ramp Up	0–2 seconds, 1-second resolution					
Ramp Down	0–2 seconds, 1-second resolution					
Total Time	1–60 minutes					

Thigh RF Stim Unit Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating Voltage	3.7 V
Battery Type	Proprietary rechargeable Li-Ion (Lithium Ion) 3.7 V, 750 mAh
Indications	• Status (fault, battery, charging) and Stimulation LEDs • “Beeps” for audio alerts
Dimensions	• Length: 74 mm (2.9 in.) • Width: 43 mm (1.7 in.) • Height: 15 mm (0.6 in.)
Weight	50 grams (1.6 oz.)
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C (-13°F to +131°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Charging temperature: 5°C to 40°C (41°F to 104°F) • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Pulse Parameters	
Pulse	Balanced Biphasic
Waveform	Symmetric or Asymmetric
Intensity (Peak)	0–100 mA, 1-mA resolution (positive phase)
Maximum Intensity (rms)	16.5 mA (rms)
Max Voltage	120 V

	Symmetric			Asymmetric		
Positive Pulse Duration (µsec)	100	200	300	100	200	300
Negative Pulse Duration (µsec)	100	200	300	400	800	1200
Inter-Phase Interval (µsec)	50			0		
Total Pulse Duration (µsec)	250	450	650	500	1000	1500
Max Load	5000 ohm (Subject to max voltage limitation)					
Pulse Repetition Rate	20–45 Hz, 5-Hz resolution					
Gait Parameters						
Swing Control Delay (%)	0–100% of phase* time, 5% resolution					
Swing Control End (%)	0–100% of phase* time, 5% resolution					
Stance Control Delay (%)	0–100% of phase* time, 5% resolution					
Stance Control End (%)	0–100% of phase* time, 5% resolution					
Ramp Up	0–2 seconds, 0.1-second resolution					
Ramp Down	0–2 seconds, 0.1-second resolution					
Extend (%)	0–100% of stance time, 10% resolution					
Max. Duration of Stimulation	2–10 seconds, 1-second resolution					
* Stimulation burst can start either on swing or stance phase.						

L300 FS Cuff Specifications	
Material	Fabric-Polymer
Fits Limb Circumference	29–51 cm (11–20 in.)
Dimensions	• Height: 160 mm (6.3 in.) • Width: 100 mm (3.9 in.) • Depth: 125 mm (4.9 in.)
Weight	Approximately 150 grams (4.8 oz.)

Thigh FS Cuff Specifications	
Material	Skeleton–TPU; Panel Assemblies and Buckles–Silicone
Fits Limb Circumference	• Upper thigh circumference: 53 cm–85 cm (20.9 in.–33.5 in.) • Knee circumference: 33 cm–50 cm (13 in.–19.7 in.) • Thigh length: 24 cm–35 cm (9.4 in.–13.8 in.)

Dimensions	• Length: 17 cm–26 cm (6.7 in. – 10.24 in.)
	• Circumference (minimal):
	  • Proximal panel: 42 cm (16.5 in.)
	  • Distal panel, regular: 45 cm (17.7 in.)
	  • Distal panel, large: 51 cm (20.1 in.

Weight	Approximately 420 grams (14.8 oz.)

Intelli-Sense Gait Sensor Specifications	
Classification	Internally powered, continuous operation with type BF applied part(s)
Battery Type	Lithium coin cell, CR2430, 280 mAh
Dimensions of the Transmitter	• Length: 80 mm (3.2 in.) • Width: 50 mm (2.0 in.) • Height: 10 mm (0.4 in.)
Weight	35 grams (1.1 oz.)
Environmental Ranges	• Transport and storage temperature: -25°C to +55°C (-13°F to +131°F) • Operating conditions temperature: 5°C to 40°C (41°F to 104°F) • Relative humidity: 25% to 85% • Atmospheric pressure: 700 hPa to 1060 hPa

Charger Specifications	
Use medical Class II safety approved power supply provided/approved by Bioness with the following ratings:	
Input	
Voltage	100–240 V AC
Current	400 mA
Frequency	50–60 Hz
Output	
Voltage	5 V ± 5%
Current	2400 mA

Note: Do not use the NESS L300 Plus System while charging. Do not wear the L300 or Thigh FS Cuffs while charging.

Wireless Link Specifications	
Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for U.S.) regulations

L300 Electrode and L300 Electrode Base Specifications	
Hydrogel Electrodes	Two 45-mm (1.77-in.) diameter hydrogel electrodes **Note:** Use only electrodes provided by Bioness Inc.
Hydrogel Electrode Bases	Two relocatable polymer electrode bases
Cloth Electrodes	Two 45-mm (1.77-in.) diameter non-woven fabric/cloth electrodes **Note:** Use only electrodes provided by Bioness Inc.
Cloth Electrode Bases	Two relocatable polymer electrode bases

Thigh FS Cuff Cloth Electrode Specifications	
Material	Non-woven cloth **Note:** Use only electrodes provided by Bioness Inc
Dimensions	Proximal: Oval, 130 mm x 75 mm (5.1 in. X 3 in.); Distal: Oval, 120 mm x 63 mm (4.7 in. X 2.5 in.)

Appendix - EMI Tables

System Characteristics	
Transmitters	
Operating Frequency Band	2401–2482 MHz
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Radiated Power	<10 dBm
Receivers	
Operating Frequency Band	2401–2482 MHz
Receiver Bandwidth	812 kHz around a selected frequency

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF emissions CISPR 11	Group 1	The NESS L300 Plus System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NESS L300 Plus System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration— Electromagnetic Immunity for All Equipment and Systems			
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment— Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line (Class II without any grounded interconnections)	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NESS L300 Plus System requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The NESS L300 Plus System is intended for use in the electromagnetic environment specified below. The customer or the user of the NESS L300 Plus System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the NESS L300 Plus System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	**Recommended separation distance:** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	$[E_1] = 10$ V/m in 26 MHz to 1 GHz $[E_1] = 3$ V/m in 1 GHz to 2.5 GHz	**Recommended separation distance:** $d = 0.4\sqrt{P}$, 80–800 MHz range $d = 0.7\sqrt{P}$, 800–1000 MHz range $d = 2.3\sqrt{P}$, 1000–2500 MHz range

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
NOTE 3: *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol:

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NESS L300 Plus System is used exceeds the applicable RF compliance level above, the NESS L300 Plus System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NESS L300 Plus System.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NESS L300 Plus System

The NESS L300 Plus System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NESS L300 Plus System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NESS L300 Plus System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz Outside ISM Bands **d = 1.2√P**	**80 MHz to 800 MHz** **d = 0.4√P**	**800 MHz to 1000 MHz** **d = 0.7√P**	**1000 MHz to 2.5 GHz** **d = 2.3√P**
0.01	4.7 in. (0.12 m)	1.6 in. (0.04 m)	2.8 in. (0.07 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	5.2 in. (0.13 m)	8.7 in. (0.22 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15 ft 7 in. (0.4 m)	2 ft 4 in. (0.7 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.3 m)	7 ft 3 in. (2.2 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	23 ft (7 m)	75 ft 6 in. (23 m)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: All calculations were made according to tables 204 and 206 of IEC 60601-1-2 for not life-supporting equipment using factors of 3.5 in 0.15–800 MHz and 7 in 800–2500 MHz. There are no requirements for ISM bands in these tables.